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**Datasheet for the decision
of 7 July 2022**

Case Number: T 0513/20 - 3.3.08

Application Number: 13169693.2

Publication Number: 2634243

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C12N5/071, B01D15/26,
B01D69/08, C07K16/00, C07K1/18,
C07K1/22, C07K1/34

Language of the proceedings: EN

Title of invention:
Improved process for the culturing of cells

Patent Proprietor:
Patheon Holdings I B.V.

Opponents:
Baxalta GmbH
Boehringer Ingelheim Pharma GmbH & Co. KG /
Boehringer Ingelheim International GmbH
Repligen Corporation

Headword:
Cell culturing/PATHEON

Relevant legal provisions:

EPC Art. 111(1)

EPC R. 80

RPBA Art. 12(4)

Keyword:

Main request - amendment occasioned by a ground for opposition
- (yes)

Auxiliary request 1 - amendment occasioned by a ground for
opposition - (yes)

Appeal decision - remittal to the department of first instance
- (yes)

Decisions cited:

T 0750/11

Catchword:



Beschwerdekammern

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Case Number: T 0513/20 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 7 July 2022

Appellant:

(Patent Proprietor)

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 3 January 2020
revoking European patent No. 2634243 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman B. Stolz
Members: M. Montrone
D. Rogers

Summary of Facts and Submissions

- I. The appeal lies against the decision of an opposition division to revoke European patent No. 2 634 243. This patent is based on European patent application No. 13 169 693.2 ("patent application") which is a divisional of the earlier patent application No. 07765049.7 published as International patent application WO 2008/006494 ("earlier patent application").
- II. The opposition division revoked the patent because the main request and auxiliary request 1 were found not to comply with the requirements of Rule 80 EPC. In claim 1 of both requests the term "*using tangential flow*" was replaced by "*cross-flow*". Both terms, however, were found to be synonyms in line with a submission of the patent proprietor (see document D62, page 2, last paragraph), and in view of page 6, lines 24 to 27 of the earlier patent application (see decision under appeal, points 11.2 to 11.4). Although grounds of opposition were invoked by opponent 01, the opposition division failed to see which ground could justify an amendment based on replacing a term by its synonym.

In particular, it was held that the amendment in claim 1 did not represent a meaningful and comprehensible attempt to overcome potential objections under Article 100(a) in conjunction with Article 54 EPC. While the amendment in claim 1 could address an objection under Article 100(c) EPC in principle, the opposition division considered that the situation in this case was different. Opponent 01 raised an objection under added subject-matter not against the feature "*tangential flow*" as such, but against the combination of features cited in claim 1. Although the opposition division

shared in their preliminary opinion opponent 01's view that the application as filed provided no basis for selecting "*tangential flow*" from the possibilities disclosed in the application as filed, these objections did not call for replacing "*tangential flow*" by its equivalent "*cross-flow*".

Furthermore, the identical meaning of both terms was acknowledged by the opposition division in parallel proceedings. This was not changed by the disclosure of document D36 (see point 7, page 1482), since nothing in this document pointed at a meaning of "*cross-flow*" that differed from "*tangential flow*".

- III. With their statement of grounds of appeal, the patent proprietor ("appellant") submitted a main request and auxiliary request 1, which are identical to the respective sets of claims submitted during the first instance proceedings.
- IV. In reply, opponent 01 ("respondent") submitted arguments against the admission of the main request and auxiliary request 1 into the appeal proceedings.
- V. In reply to the summons, opponent 02 informed the board that they would not attend the oral proceedings. Opponent 03 had already withdrawn their opposition during the first instance proceedings.
- VI. In a communication in preparation of oral proceedings, the parties were informed that the board was inclined to admit into the proceedings the main request and auxiliary request 1. Further to this, the board informed the parties that it was inclined to set aside the decision under appeal and to remit the case to the opposition division for further prosecution.

VII. In reply, the appellant and the respondent informed the board that they were not going to attend the oral proceedings.

VIII. Accordingly, the board cancelled the oral proceedings, and informed the parties that the proceedings continued in writing.

IX. Claim 1 of the main request reads:

"1. Process for the culturing of eukaryotic cells in a reactor in suspension in a cell culture medium, wherein the cells produce a desired biological substance selected from proteins and vaccines, which can be used as an active ingredient in a pharmaceutical preparation, wherein at least one cell culture medium component is fed to the cell culture and wherein the cell culture comprising the cells, the desired biological substance and cell culture medium is circulated over a filter in cross-flow and wherein the filter has a pore size characterized by a molecular weight cut-off of at least 30 kDa and at most 100 kDa, suitable to separate the desired biological substance from substances having a lower molecular weight than the desired biological substance, wherein the liquid outflow from the filter essentially only contains components having a molecular weight lower than that of the desired biological substance and wherein the desired biological substance is retained in or fed back into the reactor".

X. Claim 1 of auxiliary request 1 reads:

"1. Process for the culturing of eukaryotic cells in a reactor in suspension in a serum free cell culture medium, wherein the cells produce a desired biological substance selected from proteins and vaccines, which can be used as an active ingredient in a pharmaceutical preparation, wherein at least one cell culture medium component is fed to the cell culture and wherein the cell culture comprising the cells, the desired biological substance and cell culture medium is circulated over a filter in cross-flow and wherein the filter has a pore size characterized by a molecular weight cut-off of at least 30 kDa and at most 100 kDa, suitable to separate the desired biological substance from substances having a lower molecular weight than the desired biological substance, wherein the liquid outflow from the filter essentially only contains components having a molecular weight lower than that of the desired biological substance and wherein the desired biological substance is retained in or fed back into the reactor".

XI. The following documents are cited in this decision:

D11: US 4,806,484 (published 21 February 1989);

D36: Koros W.J., *et al.*, Pure & Applied Chemistry, 1996, 1479-1489;

D62: Patent proprietor's submissions of 4 October 2019;

D63: Patent proprietor's submissions of 30 October 2018;

D64: Notice of opposition filed by opponent 01 on 30 May 2018;

D66: Opponent 01's submission dated 11 November 2019.

- XII. The appellant's written submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission into the appeal proceedings of the main request and of auxiliary request 1

The main request and auxiliary request 1 corresponded to auxiliary requests 2 and 6 submitted with the letter dated 4 October 2019 in reply to the preliminary opinion annexed to the summons, and within the period specified in Rule 116 EPC. The replacement of the feature "*using a tangential flow*" by "*cross-flow*" in claims 1 of these two sets of claims was occasioned by a ground for opposition invoked by the respondent. In particular, this amendment addressed an objection under Articles 100(a) and 54 EPC in view of document D11, and under Article 100(c) EPC. These two sets of claims should thus be admitted into the proceedings under Rule 80 EPC.

- XIII. The respondent's written submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission into the appeal proceedings of the main request and of auxiliary request 1

The opposition division was correct in not admitting under Rule 80 EPC the main request and auxiliary request 1 into the proceedings.

As regards claim 1 of the main request, the appellant stated themselves that tangential flow and cross-flow had the same meaning (see documents D62, page 2, last paragraph, and D63, point 2.1.2). The use of equivalent terms did not represent a serious attempt to address a novelty issue. There was also no inconsistency between the opposition division's position on the admission of the main request and the decision on lack of novelty in a parallel case, since these were separate decisions on separate sets of claims.

Furthermore, the replacement of "*tangential flow*" by "*cross-flow*" in claim 1 of the main request did not overcome the issue of added subject-matter. The application as filed did not point on page 6, lines 23 to 26 at any flow type, neither tangential nor cross-flow. Nor was claim 6 as filed incorporated into the patent application. Consequently, this claim did not form a basis for "*cross-flow*" either.

Claim 1 of auxiliary request 1 was identical to claim 1 of the main request, except that the feature "*serum free*" was added. Claim 1 of auxiliary request 1 therefore contained the same deficiency regarding "*cross-flow*" as the main request. Since it was established case law that all amendments in opposition proceedings had to represent serious attempts to overcome a ground of opposition, auxiliary request 1 failed in doing so. The non-admission of auxiliary request 1 was thus correct.

XIV. The appellant requested that the decision under appeal be set aside, and that the case be remitted to the opposition division for further prosecution.

- XV. The respondent requested that the appeal be dismissed. Conditionally, in case the board overturned the opposition division's decision on the non-admission of the main request and auxiliary request 1, the respondent requested that the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

Admission into the appeal proceedings of the main request and of auxiliary request 1

1. According to the established case law the function of an appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by an examining or opposition division. The admission (consideration) of *inter alia* claim requests into the appeal proceedings is at the board's discretion (Article 114(2) EPC and Articles 12(4) and 13(1) RPBA 2007; see Case Law of the Boards of Appeal of the EPO, 9th edition 2019 ("Case Law"), V.A.1, 1133 and V.A.4, 1206).
2. The present main request and auxiliary request 1 were filed as auxiliary requests 2 and 6, respectively during the first instance proceedings. Both requests were not admitted into the proceedings by the opposition division under Rule 80 EPC. The replacement of the terms "*using a tangential flow*" by "*in cross-flow*" in claim 1 of both sets of claims was not found to be occasioned by a ground of opposition as specified in Rule 80 EPC (see decision under appeal, points 11 to 15.2).
3. Rule 80 EPC sets out that a patent proprietor may react to the opponent's objections by amending the

description, claims and drawings, provided that the amendments are occasioned by the grounds for opposition specified in Article 100 EPC, even if the respective ground has not been invoked by the opponent.

4. The appellant submitted in their statement of grounds that the contested amendments in claims 1 of the main request and in auxiliary request 1 were occasioned by objections under Articles 100(a) and 54 EPC, and Article 100(c) EPC. Objections on these grounds were raised by the respondent in their notice of opposition ("Notice", see D64). Furthermore, claim 1 of these sets of claims were amended in view of the opposition division's preliminary opinion annexed to the summons.
5. The respondent submitted that the replacement of equivalent terms did not represent a serious attempt to overcome a ground of opposition, in particular not under Articles 100(a) and 54 EPC, and Article 100(c) EPC.
6. For assessing whether or not the main request, and/or auxiliary request 1 comply with the requirements of Rule 80 EPC, a closer look at the file history is necessary.
 - 6.1 The respondent submitted in their Notice under added subject-matter that the combination of features in claim 1 as granted had neither a basis in the patent application, nor in the earlier patent application. *Inter alia* the feature "*tangential flow*" of claim 1 was mentioned in this context (see document D64, page 8, second paragraph, and page 9, fourth paragraph). Furthermore, the respondent raised an objection against the claimed process under lack of novelty over the disclosure of several prior art documents, including

document D11 (cited as D10 in document D64, see page 19). In their feature analysis, the respondent mentioned *inter alia* that document D11 disclosed the feature "*tangential flow*" (see document D64, page 20, third paragraph to page 21, second and third paragraph, Figures A) and B)).

7. The opposition division stated in their preliminary opinion annexed to the summons under Article 100(c) EPC in point 8.2, that "*The parental application as filed states that different kinds of separation systems can be used (p. 4, l. 33 to p. 7, l. 9). In particular, "[T]he circulation of the cell culture over a filter may be a flow substantially perpendicular with respect to the filter surface, also known as dead-end flow or a flow substantially parallel to the filter surface, also known as tangential flow, for example unidirectional tangential flow (TFF) or cross-flow. A preferred example of cross-flow is alternating tangential flow (ATF) as with ATF it was found that filter clogging does not occur (quickly) even at very high cell densities". No particular emphasis can be recognised for the now claimed tangential flow" (emphasis added). The opposition division's preliminary view was therefore that claim 1 did not comply with the requirements of Article 76 EPC (see point 8.3).*

- 7.1 Furthermore as regards novelty (Article 100(a) with Article 54 EPC), the opposition division stated in point 11.1 of the preliminary opinion that while they agreed with the patent proprietor that dialysis was fundamentally different from tangential flow filtration, claim 1 as granted did not refer to "*tangential flow filtration*" but mentioned "*circulating the cell culture medium "over a filter using a tangential flow"*". This may be understood to merely

indicate the direction of the flow (tangential and not perpendicular to the filter)" (emphasis added).

- 7.2 In view of this claim construction the opposition division indicated in their preliminary opinion in the context of document D11 (see point 11.4), that *"It therefore needs to be discussed at the oral proceedings whether the expression "wherein the cell culture [...] is circulated over a filter using a tangential flow" distinguishes the subject-matter of claim 1 from the dialysis disclosed in D11"*.
8. The appellant submitted in reply thereto (see document D62), *inter alia* auxiliary requests 2 and 6. These claim sets were later renamed as main request and auxiliary request 1 during the oral proceedings, while all other sets of claims were withdrawn (see point 8 of the decision under appeal).
- 8.1 The appellant indicated on page 9, point 2 of their submission D62 that the replacement of *"tangential flow"* by *"cross-flow"* in auxiliary request 2 addressed the opponents' objections under Articles 100(a) in combination with Article 54 EPC, as well as under Article 100(c) EPC. Reference was made in this context to document D36.
- 8.2 Document D62 further mentions that auxiliary request 6 (i.e. auxiliary request 1 in appeal) combined the amendments of auxiliary requests 2 and 3 (see page 10, point 6). The amendments in auxiliary request 6 were introduced to address objections under Articles 100(a), 54 and 56 EPC, and Article 100(c) EPC (see page 9, points 2 and 3).

9. In reply thereto, the respondent raised objections against the admissibility of auxiliary request 2 (i.e. the main request in appeal, see page 18 of document D66). The respondent submitted that the feature "*cross-flow*" in claim 1 was taken from the description which raised additional issues adding to the complexity of the case. Rule 80 EPC was mentioned, and the respective passage under this heading refers to a sentence in the appellant's submission D62 which states that "*tangential flow and cross-flow in the first passage have to be understood as being the same*" (see page 2, last paragraph). In other words, according to document D62, and hence in the appellant's own view, the terms "*tangential flow*" and "*cross-flow*" as used in the patent application were synonyms. The mere replacement of a feature by its synonym contravened the requirements of Rule 80 EPC for this reason alone. Since claim 1 of auxiliary request 6 cited "*cross-flow*" too, the objections raised against auxiliary request 2 under admissibility applied *mutatis mutandis* for auxiliary request 6 (see document D66, page 27).

10. In summary, the file history reveals that the main request and auxiliary request 1 were submitted during the written phase of the opposition proceedings before the final date for making written submissions in preparation of oral proceedings under Rule 116(1) EPC.

- 10.1 The term "*cross-flow*" was introduced in claims 1 of both requests, filed as auxiliary requests 2 and 6 in reply to the preliminary opinion of the opposition division annexed to the summons. Articles 100(a) and 54 EPC and Article 100(c) EPC were invoked by the respondent in their Notice against claim 1 as granted, *inter alia* against the combination of features comprising "*tangential flow*". The objections under

Article 100(c) EPC were shared by the opposition division in their preliminary opinion annexed to the summons, while doubts remained regarding Articles 100(a) and 54 EPC.

- 10.2 Thus at the time auxiliary requests 2 and 6 (i.e. main request, and auxiliary request 1 in the appeal) were submitted, the introduction of the feature "*cross-flow*" into claim 1 was an attempt to overcome objections raised under Articles 100(a) and 100(c) EPC.
11. In the decision under appeal in essence the opposition division was of the opinion that since "*tangential flow*" and "*cross-flow*" were synonyms, no ground for opposition justified this amendment.
12. The board does not agree.
- 12.1 As set out above (see point 10.2), at the time the appellant filed auxiliary requests 2 and 6, both requests were filed in an attempt to address objections raised under Articles 100(a) and (c) EPC. This is uncontested. The contested issue is whether or not the amendment (i.e. the replacement of "*using a tangential flow*" by "*in cross-flow*") represents a serious attempt to overcome at least one ground for opposition (see T 750/11, point 2.3.2 of the Reasons).
- 12.2 The opposition division found that this was not the case. Firstly, based on the appellant's own feature construction and the disclosure in the earlier patent application, both terms had the same meaning. However, a replacement of synonyms was unsuitable to overcome any potential objections under Articles 100(a) and (b) EPC. Secondly, the feature "*tangential flow*" in claim 1 was not objected to in isolation under Article 100(c)

EPC, but only in combination with the remaining features of the claim.

12.3 As regards the first argument, the relevant criterion for examining the requests' admission is whether or not at the time the appellant filed them it was prima facie evident that the features "*using tangential flow*" and "*in cross-flow*" were in fact synonyms.

12.4 In the board's view, as soon as the answer to this question requires the interpretation of a feature, the question whether or not a claim complies with the requirements of Rule 80 EPC has to be answered in the positive followed by substantive examination under the respective ground for opposition. Since the contested features in claim 1 are functionally defined only, their potentially identical meaning is not *prima facie* evident, but requires claim construction.

12.5 As regards the second argument, the opposition division made a distinction between an objection under Article 100(c) EPC raised against (i) the isolated feature "*tangential flow*" cited in claim 1, and (ii) against the same feature in the context of a certain combination of claimed features. According to the opposition division, the appellant would be allowed to replace "*tangential flow*" by "*cross-flow*" if the objection was raised under the conditions of the first scenario, but not under the second scenario.

12.6 This distinction is not convincing, since in both scenarios the feature "*tangential flow*" is objected to under Article 100(c) EPC. However, under Rule 80 EPC it is irrelevant whether such an objection is directed against an isolated feature, or against the feature within a combination of features. A replacement of the

contested feature by an alternative feature for which the earlier patent application might provide a better pointer represents a serious attempt to overcome an objection under added subject-matter.

13. In view of the considerations above, the board admits the main request and auxiliary request 1 into the proceedings under Rule 80 EPC.

Remittal

14. The decision under appeal dealt solely with the question of admitting the main request and auxiliary request 1 under Rule 80 EPC. For the reasons set out above, this Rule does not prejudice the maintenance of the patent. The appeal is thus allowable and the decision under appeal is to be set aside.
15. Under Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal. It may either exercise any power within the competence of the department which was responsible for the decision appealed, or remit the case to that department for further prosecution. Under Article 11 RPBA2020 the board shall not remit a case for further prosecution to the department whose decision was appealed unless special reasons present themselves for doing so.
16. Both parties requested that the board remits the case to the opposition division for further prosecution if the decision under appeal is set aside.
17. Since the substantive examination of the present case has not yet started, and since the primary object of the appeal proceedings is to review the decision under

appeal in a judicial manner as expressed in Article 12(2) RPBA 2020, the board decides to remit the case to the opposition division for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The main request and auxiliary request 1 are admitted into the proceedings.
3. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



M. Schalow

B. Stolz

Decision electronically authenticated