Datasheet for the decision of 16 November 2009

Case Number: T 0744/08 - 3.3.08
Application Number: 98938765.9
Publication Number: 1002055
IPC: C12N 7/02
Language of the proceedings: EN

Title of invention:
Recovery of virus from cell culture using a hypertonic salt solution

Patentee:
Xenova Research Limited

Opponent:
Dr. Johann Then

Headword:
Recovery of virus/XENOVA

Relevant legal provisions:
EPC Art. 84

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: clarity (no)"
"Auxiliary request 1: clarity (no)"

Decisions cited:
G 0009/92

Catchword:
-
Case Number: T 0744/08 - 3.3.08

DECISION
of the Technical Board of Appeal 3.3.08
of 16 November 2009

Appellant: Xenova Research Limited
(Patent Proprietor)
310 Cambridge Science Park
Milton Road
Cambridge CB4 0WG (GB)

Representative: Walton, Seán
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Respondent: Dr. Johann Then
(Opponent)
Bechtenwalderstr. 70
D-65931 Frankfurt am Main

Representative: Lahrtz, Fritz
Isenbruck Bösl Hörschler Wichmann LLP
Prinzregentenstrasse 68
D-81675 München (DE)


Composition of the Board:
Chairman: P. Julià
Members: T. J. H. Mennessier
C. Heath
Summary of Facts and Submissions

I. The patentee (appellant) lodged an appeal against the decision of the opposition division dated 4 February 2008, whereby European patent No. 1 002 055 was maintained in an amended form. The patent had been granted on European patent application No. 98 938 765.9 entitled "Recovery of virus from cell culture using a hypertonic salt solution" claiming the priority date of 7 August 1997, and published under the international publication number WO 99/07834.

II. The patent had been opposed by one opponent. The grounds for opposition relied upon were lack of novelty (Article 100(a) EPC), lack of inventive step (Article 100(a) EPC) and insufficiency of disclosure (Article 100(b) EPC).

III. Basis for the maintenance of the patent was the second auxiliary request (claims 1 to 8) filed at the oral proceedings held before the opposition division on 22 May 2007. The main request, filed on 23 April 2007, and the first auxiliary request, also filed on 22 May 2007, had been refused for reasons of non-compliance with Article 84 EPC (lack of clarity) and non-compliance with Article 123(2) EPC (added matter), respectively.

IV. The statement of grounds of appeal was filed on 6 June 2008. It was accompanied by a main and two auxiliary requests (1 and 2, respectively) which corresponded to the requests considered by the opposition division.

Claim 1 of the main request reads as follows:
"1. A process of harvesting a herpesvirus from a cell culture infected therewith, which comprises treating said culture with a hypertonic aqueous salt solution in a harvesting incubation to yield a virus suspension, wherein the process is without a cell-disruption step."

Claim 1 of auxiliary request 1 reads as follows (emphasis added by the board):

"1. A process of harvesting a herpesvirus from a cell culture infected therewith, which comprises treating said culture with a hypertonic aqueous salt solution of up to 2M salt concentration in a harvesting incubation to yield a virus suspension, wherein the process is without a cell-disruption step."

V. The opponent (respondent) replied on 22 October 2008 with a letter accompanied by 6 new documents.

VI. The board on 7 August 2009 issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal in which provisional and non-binding opinions were expressed on the issues to be discussed at the scheduled oral proceedings, in particular the issue of clarity.

VII. On 21 October 2009, the appellant informed the board that it would not attend the oral proceedings and that it maintained its previous requests. In its letter, it also submitted that, although it was the case that the claims had been amended, there was no basis for a free-ranging de novo examination, in particular under Article 84 EPC, in appeal proceedings.
VIII. The submissions made by the appellant in writing, insofar as they are relevant to the present decision, may be summarised as follows:

Main request (claim 1; compliance with Article 84 EPC)

The invention was in relation to the application of hypertonic aqueous salt solution to harvesting herpesvirus, without a cell disruption step in the harvesting. No essential feature was missing in claim 1. There was no need to indicate a particular salt concentration. The skilled person knew that if the hypertonicity of the solution was too high, then the cells would be disrupted or the virus damaged. The essential feature for the invention was the avoidance of a cell disruption step.

Auxiliary request 1 (claim 1; compliance with Article 84 EPC)

The technical reality was that a possible upper limit of 2M for the salt concentration of the hypertonic solution actually to be used in performing the process of the invention was disclosed in the patent. That concentration was not an essential feature required to carry out the process, in the sense that, as for the main request, what was taught was that a hypertonic salt solution was to be used, that there was to be no cell disruption step and that the hypertonicity was to be such as to not damage the virus.
IX. The submissions made by the respondent, insofar as they are relevant to the present decision, may be summarised as follows:

Main request (claim 1; compliance with Article 84 EPC)

The feature "without a cell-disruption step" was unclear. It could mean either that there was no cell disruption at all or that no active cell disruption was performed. Furthermore, claim 1 lacked an essential feature since the feature "treating with a hypertonic salt solution" was insufficient to guarantee that there was no cell disruption.

Auxiliary request 1 (claim 1; compliance with Article 84 EPC)

The added feature of claim 1, namely the use of a hypertonic aqueous salt solution with a salt concentration of up to 2M, did not overcome the lack of clarity objection, as according to the description such a concentration did not damage the virus, whereas there was no indication that it permitted to avoid cell disruption.

X. The appellant (patentee) requests in writing that the decision under appeal be set aside and that the patent be maintained based on the main request or the auxiliary request 1, both filed by letter of 6 June 2008.

XI. The respondent (opponent) requests that the appeal be dismissed.
Reasons for the Decision

Preliminary remark

1. As the patentee is the sole appellant, the maintenance of the patent on the basis of auxiliary request 2 cannot be challenged (prohibition of reformatio in peius; see decision G 9/92 (OJ EPO, 1994, 875), point 1 of the Order).

Main request

2. As claim 1 of the main request is an amended version of claim 1 as granted and as it was objected to in the decision under appeal for reasons of lack of clarity, the board has the duty to assess whether claim 1 complies with Article 84 EPC.

3. There is no literal support or definition in the patent-in-suit for the feature "wherein the process is without a cell-disruption step", which is thus open to interpretation. The more so since, in the light of the description of the patent-in-suit, that feature might be understood either as requiring no cell disruption at all or else as contemplating a minimal, not excessive or acceptable level of cell disruption (cf. column 3, lines 4-8, 24-28 and 42-45), the latter being, however, not further characterized in the description. Therefore, the skilled person is not in a position to clearly and unambiguously determine whether none of the steps comprised in the claimed process of harvesting a herpesvirus, including the incubation step of the infected cells in contact with a hypertonic aqueous
salt solution, involves a cell disruption step or might be seen or considered as such a step. This ambiguity renders the claim unclear, as it does not allow a precise definition of the subject-matter for which protection is sought.

4. Therefore, the board concludes that the main request does not comply with the clarity requirement of Article 84 EPC.

Auxiliary request 1

5. Claim 1 of auxiliary request differs from claim 1 of the main request only in that the salt concentration has been specified to be up to 2M (see Section IV, supra). Whereas, according to page 3, column 3, lines 4 to 6 of the patent specification, this was a concentration at which the virus "can often stand", i.e. to be interpreted by the skilled person as meaning "is not damaged", there is no indication at all in the rest of the description that cell disruption may be avoided up to this specific salt concentration. Therefore, the added feature does not overcome the lack of clarity objection raised against claim 1 of the main request.

6. Thus, the board concludes that claim 1 of auxiliary request 1 is unclear for the very same reasons given at point 3 supra with respect to claim 1 of the main request and that, therefore, auxiliary request 1 does not comply with the clarity requirement of Article 84 EPC.
Concluding remark

7. As none of the requests on file other than the request accepted by the opposition division can form a basis for the maintenance of the patent in amended form, the appeal should be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski P. Julià