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**Datasheet for the decision
of 10 December 2015**

Case Number: T 1990/10 - 3.3.08

Application Number: 02740758.4

Publication Number: 1412486

IPC: C12N7/02

Language of the proceedings: EN

Title of invention:
METHOD FOR VIRUS PROPAGATION

Patent Proprietor:
Bavarian Nordic A/S

Opponents:
Sanofi Pasteur, Inc.
TRANSGENE S.A.
Oxford Biomedica (UK) Limited
Emergent Product Development UK Limited

Headword:
Amplification poxvirus temperature range cultivation chicken
embryo fibroblasts/BAVARIAN NORDIC

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Main Request, Auxiliary Requests 1-5
claim request upheld at first instance -
- added subject-matter (yes)

Decisions cited:
T 0002/81

Catchword:



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Chambres de recours**

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Case Number: T 1990/10 - 3.3.08

**D E C I S I O N
of Technical Board of Appeal 3.3.08
of 10 December 2015**

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
27 July 2010 concerning maintenance of the
European Patent No. 1412486 in amended form.

Composition of the Board:

Chairman M. Wieser
Members: P. Julià
D. Rogers

Summary of Facts and Submissions

- I. European patent no. 1 412 486 is based on European patent application no. 02 740 758.4, published as WO 03/008533 (hereinafter "*the application as filed*"), and was granted with 16 claims. The patent was opposed by three parties (opponents 01, 02 and 04) on the grounds as set forth in Articles 100(a), (b) and (c) EPC. Opponent 03 withdrew its appeal.

The opposition division considered the Main Request (claims as granted) to contravene Article 123(2) EPC and did not admit two auxiliary requests (filed on 21 April 2010 as Auxiliary Requests 1 and 2) into the opposition proceedings, because they were considered not to overcome the objection raised under Article 123(2) EPC against the Main Request. Auxiliary Request 1 (filed on 21 April 2010 as Auxiliary Request 3) was considered to contravene the requirements of Article 84 EPC and Auxiliary Requests 2 and 3 (filed on 21 April 2010 as Auxiliary Requests 4 and 5) were found not to fulfil the requirements of Article 54 EPC. The patent was maintained in amended form based on Auxiliary Request 4 filed on 23 June 2010 at the oral proceedings before the opposition division.

- II. Appeals were lodged by the patentee (appellant I) and the opponents 02 and 04 (appellants II and III).

With its Grounds of Appeal, appellant I requested, as its Main Request, that the decision under appeal be set aside and that the patent be maintained as granted. As auxiliary request, appellant I requested to maintain the patent on the basis of any of Auxiliary Requests 1 to 5 originally filed on 21 April 2010 and filed again with its Grounds of Appeal.

- With their Grounds of Appeal, appellants II and III filed new documentary evidence (A46 to A64) and requested that the decision under appeal be set aside and the patent be revoked.
- III. All appellants filed further submissions in reply to the other parties' statements of Grounds of Appeal. They all maintained their original requests. With their reply, appellants II and III filed new evidence (11 documents).
- IV. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed thereto, the parties were informed of the board's preliminary, non-binding opinion on the issues of the case. The board expressed the interim view that the decision under appeal should be set aside and the patent revoked. It was noted in the communication that appellant I had not requested that the appeals of appellants II and III be dismissed and the patent be maintained on the basis of the request upheld by the opposition division.
- V. In reply thereto, appellant I informed the board that the claim request upheld by the opposition division had never been withdrawn and that this request was part of the appeal proceedings. As a further auxiliary request, appellant I explicitly requested that the appeals of appellants II and III be dismissed and the patent be maintained on the basis of the claim request upheld by the opposition division.
- VI. With letters of 30 September 2015 and 29 October 2015, the party as of right (opponent 01) and appellant I,

respectively, informed the board, without filing substantive arguments, that they would not attend the oral proceedings.

- VII. With letters of 27 and 30 October 2015, appellants II and III, respectively, filed substantive arguments.
- VIII. On 10 November 2015, the board informed the parties that the scheduled oral proceedings were cancelled.
- IX. Claims 1 and 4 of the **Main Request** (claims as granted) read as follows:

"1. A process of amplifying a Chordopoxvirus characterized in that the virus is propagated in culture media at a cultivation temperature at about 35°C or below 35°C, wherein the chordopoxvirus is a modified vaccinia virus Ankara (MVA), preferably MVA-BN as deposited at ECACC under No. V00083008 or a derivative thereof.

4. Process of amplifying a Chordopoxvirus characterized in that the virus is propagated in chicken embryo fibroblats at a cultivation temperature of about 26°C to 32°C."

Claim 2-3 and 8 were directed to preferred embodiments of claim 1, claims 5-7 to preferred embodiments of claim 4. Dependent claims 9-16 referred back to both, claim 1 and claim 4.

- X. Claim 1 of Auxiliary Requests 1 and 2 differed from claim 1 of the Main Request only in the temperature range which was changed to read "*at about 35°C or below 33°C*" (Auxiliary Request 1) and "*at about 35°C to below*

32°C" (Auxiliary Request 2). Claim 4 of these auxiliary requests was identical to claim 4 of the Main Request.

XI. In Auxiliary Requests 3 to 5 the temperature range in claim 1 has been changed to read "at about 35°C or about 26°C to 35°C" (Auxiliary Request 3), "at about 35°C or between 28°C and 33°C" (Auxiliary Request 4), and "at about 35°C or between 28°C and 32°C" (Auxiliary Request 5). Claim 3 of all these auxiliary requests was identical to claim 4 of the Main Request.

XII. Claim 3 of the request upheld by the opposition division read as follows:

"3. Process of amplifying a Chordopoxvirus characterized in that the virus is propagated in chicken embryo fibroblasts at a cultivation temperature of about 26°C to 32°C, wherein the Chrodopoxvirus is a vaccinia virus selected from strain Elstree and modified vaccinia virus Ankara (MVA), preferably MVA-BN as deposited at ECACC under No. V00083008 or a derivative thereof."

XIII. The submissions of appellant I, insofar as they are relevant to the present decision, may be summarised as follows:

Article 100(c) EPC

According to decision T 2/81 (OJ EPO 1982, page 394, Headnote 2), a disclosure of a range of values together with an included preferred narrower range was also a direct disclosure of the two possible part-ranges lying within the overall range on either side of the narrower range. The reasoning set out for closed ranges with defined endpoints applied also to open-ended ranges.

The sole requirement set out in this decision was that the endpoint values were specifically indicated. The endpoint of the open-ended range "*below 35°C*" (claim 1) and of the range with the endpoint "*about 26°C*" (claim 4) were determinable and thus specifically indicated. The term "*about*" introduced only an error range ($\pm 0.5^\circ\text{C}$) around a value but did not change the determinability of this value. This error range was transferred to the possible part-ranges by the introduction of the term "*about*" in these part-ranges.

The disclosure of multiple temperature ranges in the application as filed could not change the fact, that the temperature ranges cited in the claims were also disclosed. According to decision T 2/81 and to the established case law, the broadest range could be combined with a preferred range but it was also possible to combine two preferred ranges and two ranges at different levels of preference with one another. Any broad range could be combined with any narrower preferred range, yielding thereby all disclosed sub-ranges. The question which range should be combined with which other range was irrelevant, because all sub-ranges resulting from combinations carried out according to the criteria set out in decision T 2/81 were part of the disclosure. In compiling a list of all explicitly disclosed ranges and of all sub-ranges resulting from these combinations, the only relevant question was whether the temperature ranges cited in claims 1 and 4 of the Main Request were in this list, and the answer thereto was positive.

The standard for determining the disclosure of the application as filed was the understanding of the skilled person in the particular case. The relevant question was therefore what the skilled person would

have understood when reading "30°C to 35°C" on page 9, line 9 of the application as filed. Since 30°C was less than 35°C, the skilled person would have unambiguously understood that this range disclosed all temperatures lower than 35°C but still higher than 30°C. The question whether the upper-endpoint 35°C was disclosed was irrelevant, since temperatures immediately below 35°C were disclosed. Moreover, according to claim 3 of the application as filed, the chordopoxvirus was propagated at a temperature of "about 30°C to about 35°C". Since the term "about" was defined as embracing temperatures in a range $\pm 0.5^\circ\text{C}$ surrounding the stated temperature, the narrower preferred range given in claim 3 specified a temperature range ending just "below 35°C", and therefore excluded the actual temperature of 35°C as recited in claim 1 of the Main Request.

The propagation of the amplified chordopoxvirus in chicken embryo fibroblasts (CEF) was disclosed on page 11, lines 7-10 of the application as filed. The temperature range "about 26°C to 32°C" was disclosed by the combination of the broad range "about 26°C to about 36°C" (page 14, line 11, claim 2 of the application as filed) with the narrower preferred range "30°C to 32°C" (page 9, line 10 and page 11, line 20 of the application as filed). The combination of the lower-endpoint of one range with the upper-endpoint of the other range resulted in the sub-range "about 26°C to 32°C". A skilled person would have understood the application as filed as describing various elements of different embodiments of the invention that could be combined with one another. The content of the application as filed had to "be taken as a whole, and not parsed into immiscible blocks of information", which would be inappropriately restrictive.

XIV. The submissions of appellants II and III, insofar as they are relevant to the present decision, may be summarised as follows:

Article 100(c) EPC

According to the criteria set out in decision T 2/81 (*supra*), the combination of the upper/lower-end values of two ranges disclosed in the application as filed did not contravene Article 123(2) EPC, if i) the end values of the range were precisely defined, ii) the combination was between the lower/upper-end values of a broader range with the upper/lower-end values of a preferred narrower sub-range, and iii) there was only a small number of ranges explicitly disclosed in the application, namely one broad range and one or two preferred sub-ranges centered around a preferred value.

The temperature range "*below 35°C*" in claim 1 of the Main Request was not directly derivable from the combination of the upper-end value of the closed range "*30°C to 35°C*" (page 9, line 9 of the application as filed) with the lower-end value of the open-ended range "*below 37°C*" (page 9, line 3 of the application as filed). The closed range "*30°C to 35°C*" encompassed all temperatures below and equal to 35°C ($\leq 35^\circ\text{C}$) and was different from a range excluding the value 35°C ($< 35^\circ\text{C}$). The lower-end value of the open-ended range "*below 37°C*" was not precisely defined and thus, the first criterion set out in decision T 2/81 was not fulfilled.

The application as filed disclosed a large number of temperature ranges and therefore, the third criterion set out in decision T 2/81 (*supra*) was also not

fulfilled. Nothing in the application as filed motivated a skilled person to fumble around with all temperature ranges disclosed in the application as filed for creating new temperature ranges. Arbitrary and *a posteriori* created combinations of end values of certain ranges disclosed in the application as filed were not allowable.

The temperature range "*about 26°C to 32°C*", in claim 4 of the Main Request, was not directly derivable from a combination of the lower-end value of the range "*about 26°C to about 36°C*" with the upper-end value of the ranges "*between 28 and 32°C*" or "*between 30°C and 32°C*" disclosed on page 9 of the application as filed. Firstly, the lower-end value was not precisely defined. Secondly, the combination was not made between the broadest range ("*below 37°C*") and a preferred sub-range, but between two preferred sub-ranges. Thirdly, the number of ranges, i.e. 11, of preferred sub-ranges, i.e. 10, and of end values of ranges and sub-ranges, disclosed in the application as filed was very large. Thus, with respect to this range, none of the criteria set out in decision T 2/81 was fulfilled.

The temperature range "*about 26°C to 32°C*" was a selection from all possible combinations between ranges, preferred sub-ranges and their end values disclosed in the application as filed. In absence of any indication leading a skilled person to this specific temperature range, this range was new and not supported by the application as filed.

XV. Appellant I (patentee) requested that the decision under appeal be set aside and the patent be maintained as granted (Main Request) or, alternatively, on the basis of any of Auxiliary Requests 1 - 5, all filed

with its Grounds of Appeal on 3 December 2010, or, as a further auxiliary request, to dismiss the appeal of appellants II and III and to maintain the patent on the basis of the claim request upheld by the opposition division. In addition, appellant I requested that the new evidence submitted by appellants II and III in the appeal procedure not be admitted.

- XVI. Appellants II and III (opponents 02 and 04, respectively) requested that the decision under appeal be set aside and the patent be revoked. In addition, appellants II and III requested that their new evidence, submitted in the appeal procedure, be admitted.
- XVII. No submissions and requests are on file from opponent 01 (party as of right). Opponent 03 withdrew its opposition with letter dated 27 January 2003 and is not a party to the present appeal proceedings.

Reasons for the Decision

Cancellation of the scheduled oral proceedings

1. In reply to the board's communication pursuant to Article 15(1) RPBA, appellants II and III filed further substantive arguments. Appellant I did not respond in substance, but, with a letter dated 30 September 2015, only informed the board in two lines that it will not attend the scheduled oral proceedings (cf. points VI-VII *supra*).
2. By its decision not to attend the scheduled oral proceedings and not to file substantive arguments in reply to the board's communication, appellant I has

chosen not to make use of the opportunity to comment on the board's opinion, either in written form or orally at oral proceedings. This was done although the board's preliminary opinion was clearly in appellant I's disfavour, i.e. "*the board is of the preliminary, non-binding opinion that the decision under appeal is to be set aside and the patent to be revoked*" (cf. page 14, point 26 of the board's communication).

3. In the light thereof, the board decided to cancel the oral proceedings scheduled for 1 December 2015.

Main Request (claims as granted)

Article 100(c) EPC (Article 123(2) EPC)

4. It has to be decided whether the application as filed provides a basis for the temperature ranges "*below 35°C*" in claim 1 and "*about 26 to 32°C*" in claim 4.

The disclosure of the application as filed

5. The application as filed concerns a method for preparing pox-viruses, in particular Chordopoxviruses, characterized by cultivation of (infected, virus producing) host cells at specific temperatures (cf. *inter alia*, page 1, lines 3-5, page 6, lines 3-11, page 9, lines 19-26, page 14, lines 4-8 and claim 1). Various temperatures are disclosed, both specific temperature values, such as the most preferred temperature "*30°C*" (cf. *inter alia*, page 9, lines 6 and 10, page 11, lines 16 and 21), as well as temperature ranges, such as the broadest temperature range "*below 37°C*" (cf. *inter alia*, page 1, line 5, page 6, line 11, page 11, line 14, page 14, line 8 and claim 1).

6. The disclosed temperature ranges differ in nature and character. Some of them are open-ended, some are closed ranges with defined upper and lower-end values, and some are nested ranges. There are rather broad ranges, such as "30°C to 36.5°C" (cf. page 9, line 8 and page 11, line 20), and rather narrow ones, such as "30°C to 32°C" (cf. page 9, line 10 and page 11, line 20). The narrower temperature ranges are defined as sub-ranges comprised within broader ranges and are defined by the terms "*preferably*", "*more preferably*" and "*most preferably*".

7. A further layer of variation is introduced by using the term "*about*" which is defined as referring "***preferably*** to the specifically mentioned temperatures and to temperatures being up to 0.5°C higher or lower than the specifically mentioned temperatures" (emphasis added by the board) (cf. page 9, lines 11 to 17). Thus, temperature values specifically mentioned in the application as filed are to be taken at their face value and temperature values accompanied by the term "*about*" are to be taken as the center of a small temperature range, encompassing temperatures "*being up to 0.5°C higher or lower*". In the application as filed, the term "*about*" is used to characterize both, specific temperature values, such as "*about 30°C*" (cf. *inter alia*, page 14, line 20 and claim 4), as well as temperature ranges. In the second case, the upper-end and lower-end values of nested and closed ranges, independent of their breadth, are preceded by the term "*about*", see for instance "*between about 26°C and about 36°C*", "*about 26°C to about 36°C*" and "*about 30°C to about 33°C*" (cf. page 9, line 4, page 14, lines 11 and 17).

8. All indications of temperature, such as ranges, sub-ranges and specific values, are disclosed in the application as filed in a particular context. In the broadest context, there is no limitation to the type of poxvirus and of the infected host cell used for propagating the virus. In the narrowest context, the poxvirus is a specific chordopoxvirus, namely a "*modified vaccinia virus Ankara (MVA), preferably MVA-BN as deposited at ECACC under No. V00083008*" (cf. page 7, lines 20-22, page 8, lines 11-14 and claim 10), and the infected host cells are chicken embryo fibroblast cells suitable for propagating the vaccinia viruses (cf. page 11, lines 7-10, claim 14).

The open-ended temperature range "below 35°C" in claim 1

9. Appellant I does not contest that the temperature range "*below 35°C*" is not explicitly disclosed in the application as filed, however, it argues that this open-ended range is implicitly derivable from the application as filed.
10. The term "*below*" is explicitly disclosed in the application as filed, only for defining the broadest mentioned temperature range, namely "*below 37°C*".
11. Appellant I argues that, in line with the criteria set out in the decision T 2/81 (*supra*), the range "*below 35°C*" is implicitly derivable from the broadest open-ended range "*below 37°C*" in combination with the upper-end value of the closed range "*30°C to 35°C*" (cf. point XIII *supra*).

However, applying the criteria set out in the decision T 2/81 (*supra*), the combination of the lower-end and the upper-end values of the closed range with the

broadest temperature range results in the temperature ranges "30°C to below 37°C" and "35°C to below 37°C". Both mixed ranges are different from the open-ended temperature range "below 35°C" present in claim 1 of the Main Request.

In agreement with appellants II and III, the board takes also the view that the closed temperature range "30°C to 35°C" includes the specific temperature "35°C" whereas the open-ended range "below 35°C" in claim 1 explicitly excludes this value (cf. point XIV *supra*).

12. Appellant I seems to argue that the closed range "30°C to 35°C" encompasses values which are "below 35°C", which, allegedly, can be described by using the terminology used in the context of the broader open-ended range "below 37°C". The board disagrees as this is not a combination of ranges and sub-ranges as defined in decision T 2/81 (*supra*). It merely amounts to the direct transfer of the term "below", which defines the openness of a disclosed broad range ("below 37°C"), to the upper end value of another temperature range disclosed in the application as filed ("30°C to 35°C"). In the absence of any indication in the application as filed to do so, this transfer of the term "below" to another temperature value or temperature range has no basis in the application as filed.
13. Thus, claim 1 does not fulfil the requirements of Article 123(2) EPC.

The temperature range "about 26°C to 32°C" in claim 4

14. The temperature range "about 26°C to 32°C" in claim 4 defines the cultivation temperature for propagating a

Chordopoxvirus in specific infected host cells, i.e. chicken embryo fibroblasts (cf. point IX *supra*).

15. The application as filed refers, according to its broadest disclosure, to the propagation of pox-virus in general and Chordopoxviruses in particular without defining the infected host cells (cf. page 8, line 25 to page 9, line 17).

In this context, numerous temperature values and ranges are disclosed on page 9, lines 3 to 10: "... at a temperature below 37°C, preferably between 36.5°C and 26°C or between about 26°C and about 36°C, more preferably between 28°C and 33°C, even more preferably between 28°C and 32°C, most preferably at 30°C. Another preferred temperature range is 30°C to 36.5°C. Particularly good results have been obtained in the subranges 30°C to 35°C, 30°C to 33°C and 30°C to 32°C. The most preferred temperature is 30°C". It is also in this context that the term "about" is defined (cf. page 9, lines 12-17). On page 14, lines 4 to 20, under the heading "Summary of the Invention", the following temperature values and ranges are given: "below 37°C", "about 26°C to about 36°C", "about 28°C to about 33°C", "about 30°C to about 33°C" and "about 30°C".

In the application as filed, the term "about" is found only in this general context and, when present in a temperature range, the term is present in both upper-end and lower-end values of the range.

16. Claims 1 to 4 as originally filed refer to temperature ranges similar to those cited under the heading "Summary of the Invention", namely "below 37°C", "about 26°C to about 36°C", "about 30°C to about 35°C" and "about 30°C", respectively.

Claim 14, directed to a *"process according to anyone of claims 1 to 13, wherein the poxvirus is propagated in chicken embryo fibroblast cells"*, by virtue of its dependency refers to all temperature ranges defined in claims 1 to 4, including the range *"about 26°C to about 36°C"* of claim 2.

The temperature range *"about 26°C to 32°C"* in claim 4 of the Main Request is neither disclosed in claims 1 to 4 as originally filed nor in the *"Summary of the Invention"*.

17. Basis for the propagation in Chicken Embryo Fibroblasts (CEF) can be found on page 11, lines 7 to 21 of the application as filed, where it is stated that *"(i)t was particularly unexpected that the process according to the present invention can be used for CEF cells since chicken have a normal average body temperature of 41°C"*.

Immediately after this passage, the preferred temperature values and ranges for this embodiment of the invention are disclosed. These are *"below 37°C"* and three nested (sub)ranges (*"between 36.5°C and 26°C"*, *"between 28°C and 33°C"* and *"between 28°C and 32°C"*) and the *"most preferably [temperature] of 30°C"* (cf. page 11, lines 13-19). In this context, it is again emphasized that these temperatures *"are so different from the normal body temperature of the chicken that one would have assumed that these cells can not be used for the propagation of vaccinia viruses"* (cf. page 11, lines 16-19).

In the sentence following immediately thereafter, three further temperature ranges are disclosed, namely *"30°C"*

to 36.5°C", "30°C to 33°C" and "30°C to 32°C" (cf. page 11, lines 19-21), which result from the straightforward combination of the most preferred temperature "30°C" with all upper-end values of the above mentioned nested ranges.

Significantly, there is no explicit disclosure of a range resulting from the combination of the most preferred temperature "30°C" with the lower-endpoints of the disclosed nested ranges. More significantly, none of the disclosed temperature ranges makes use of the term "about" and, therefore, there is no possible combination resulting in the temperature range "about 26°C to 32°C" of claim 4 of the Main Request.

18. In order to arrive at the temperature range "about 26°C to 32°C", it is necessary to combine the lower-end value of the range "about 26°C to about 36°C" in original claim 2 with the upper-end of either "between 28°C and 32°C" or "30°C to 32°C" described on page 11 of the application as filed. While these last two ranges are found in the specific context of CEF cells as host cells, the former range is found in the context of the broadest disclosure of the application as filed which does not refer to specific host cells.

19. Moreover, the combination referred to above results in a mixed temperature range "about 26°C to 32°C" which has a specific "closed" upper-end value ("32°C") and an "open" lower-endpoint ("about 26°C"). As discussed in point 7 above, the term "about" is defined in the application as filed as only "preferably" limiting the specific temperature indicated to "0.5°C higher or lower". This mixed range, with the term "about" defining only one end value of a temperature range, cannot be derived from the application as filed. Such

mixed range could only be obtained if the term "about", and thereby its definition (preferably $\pm 0.5^{\circ}\text{C}$), was transferred to all temperatures and temperature ranges disclosed in the application as filed. In the absence of any indication thereto in the application as filed, this transfer is not directly and unambiguously derivable therefrom (cf. point 12 *supra*).

20. Thus, claim 4 contains subject-matter which extends beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

Auxiliary Requests 1-5 and the request upheld by the opposition division

Article 100(c) EPC (Article 123(2) EPC)

21. Since all these requests either in claim 4 (Auxiliary Requests 1 and 2) or claim 3 (Auxiliary Requests 3 to 5 and the request upheld by the opposition division) refer to the temperature range "about 26°C to 32°C " (cf. points X, XI and XII *supra*), none of them fulfils the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside and the patent is revoked.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated