BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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

Datasheet for the decision of 18 September 2009

Case Number: T 0623/08 - 3.3.08

Application Number: 03002037.4

Publication Number: 1325960

IPC: C12N 7/01

Language of the proceedings: EN

Title of invention:
Negative strand RNA virus vector having autonomously replicating activity

Applicant:
Dnavec Research Inc.

Headword:
RNA virus/DNAVEC

Relevant legal provisions:
EPC Art. 83

Relevant legal provisions (EPC 1973):
-

Keyword:
"All requests: sufficiency of disclosure (no)"

Decisions cited:
G 0010/93

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0623/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 18 September 2009

Appellant: Dnavec Research Inc.
25-11 Kannondai 1-chome
Tsukuba-shi,
Ibaraki 305...(JP)

Representative: Goddar, Heinz J.
Forrester & Boehmert
Pettenkoferstraße 20-22
D-80336 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 9 October 2007 refusing European patent application No. 03002037.4 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Heath

Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division dated 9 October 2007, whereby the European patent application No. 03 002 037.4 with publication number 1 325 960 was refused. The application, entitled "*Negative strand RNA virus vector having autonomously replicating activity*", was filed on 28 January 2003 as a divisional application to the application No. 96 935 402.6 filed on 22 October 1996.

II. Basis for the refusal was the main request filed on 17 August 2007 and the auxiliary request filed with letter of 11 December 2006.

III. The main and the auxiliary requests were refused for reasons of lack of clarity (Article 84 EPC) and presence of added matter (Article 123(2) EPC), respectively.

IV. On 19 February 2008, the appellant filed a statement setting out the grounds of appeal which was accompanied by a main request and four auxiliary requests. The main request and the fourth auxiliary request corresponded to, respectively, the main request and the auxiliary request of the decision under appeal. Three additional documents (D9 to D11, see Section VII *infra*) were submitted.

V. Claim 1 of each of the requests on file read as follows:

Main request

"1. A complex comprising
- an RNA molecule derived from a specific disseminative negative strand RNA virus, wherein said RNA molecule is defective in that at least one gene related to the disseminative capability of the original virus is deleted or inactivated,
and
- viral structural components containing no nucleic acid,
wherein said complex has the cell infectivity and is capable of autonomously replicating RNA, but is deficient in disseminative capability."

First auxiliary request

"1. A complex comprising
- an RNA molecule derived from a specific disseminative negative strand RNA virus, **wherein said specific disseminative negative strand RNA virus is a negative strand RNA having non-segmented genome and wherein said specific disseminative negative strand RNA virus is selected from the group of Sendai virus, Newcastle disease virus, mumps virus, measles virus, respiratory syncytial virus, rinderpest virus of cattle and canine distemper virus of Paramyxoviridae,**
wherein said RNA molecule is defective in that at least one gene related to the disseminative capability of the original virus is deleted or inactivated,
and

- viral structural components containing no nucleic acid,
wherein said complex has the cell infectivity and is capable of autonomously replicating RNA, but is deficient in disseminative capability."

(the text in bold was added by the appellant in order to highlight the differences in respect of claim 1 of the main request)

Second auxiliary request

"1. A complex comprising
- an RNA molecule derived from a specific disseminative negative strand RNA virus, **wherein said specific disseminative negative strand RNA virus is a negative strand RNA having non-segmented genome and wherein said specific disseminative negative strand RNA virus is selected from the group of Sendai virus, Newcastle disease virus, mumps virus, measles virus, respiratory syncytial virus, rinderpest virus of cattle and canine distemper virus of Paramyxoviridae,**
wherein said RNA molecule is defective in that at least one gene related to the disseminative capability of the original virus is deleted or inactivated,
and
- viral structural components containing no nucleic acid,
wherein said complex has the cell infectivity and is capable of autonomously replicating RNA, but is deficient in disseminative capability,
wherein by disseminative capability is meant the capability to form infectious particles or their equivalent complexes and disseminate them to other

cells following the transfer of nucleic acid into host cells by infection of artificial techniques and the intracellular replication of said nucleic acid."

(the text in bold was added by the appellant in order to highlight the differences in respect of claim 1 of the main request)

Third auxiliary request

"1. A complex comprising
- an RNA molecule derived from a specific disseminative negative strand RNA virus, **wherein said specific disseminative negative strand RNA virus is a negative strand RNA having non-segmented genome and wherein said specific disseminative negative strand RNA virus is selected from the group of Sendai virus, Newcastle disease virus, mumps virus, measles virus, respiratory syncytial virus, rinderpest virus of cattle and canine distemper virus of Paramyxoviridae,**
wherein said RNA molecule is defective **in at least a part of structural genes but normal in genes for the replication enzyme group,**
and
- viral structural components containing no nucleic acid,
wherein said complex has the cell infectivity and is capable of autonomously replicating RNA, but is deficient in disseminative capability."

(the text in bold was added by the appellant in order to highlight the differences in respect of claim 1 of the main request)

Fourth auxiliary request

"1. A complex comprising
- an RNA molecule derived from a specific disseminative negative strand RNA virus,
wherein said RNA molecule is defective in at least a part of structural genes in that at least one gene corresponding to the M, F and HN gene of Sendai viral RNA is deleted or inactivated,
and
- viral structural components containing no nucleic acid,
wherein said complex has the cell infectivity and is capable of autonomously replicating RNA, but is deficient in disseminative capability."

(the underlining was added by the appellant in order to highlight the differences in respect of claim 1 of the main request)

VI. The examining division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC).

VII. The following documents are cited in the decision:

(D1) EP 0 440 219 A1 (published on 7 August 1991)

(D2) WO 94/08022 (published on 14 April 1994)

(D7) Y. Nagai and A. Kato, Microbiol. Immunol., Vol. 43, No. 7, 1999, pages 613 to 624

(D8) D. C. Merz et al., J. Exp. Med., Vol. 151, February 1980, pages 275 to 288

(D9) T. Matsumoto, Microbiol. Immunol., Vol. 26, No. 4, 1982, pages 285 to 320

(D10) C. R. Pringle et al., Arch. Virol., Vol. 117, No. 1-2, 1991, pages 137 to 140

(D11) E. Norrby et al., Vet. Microbiol., Vol. 33, No. 1-4, 1992, pages 275 to 286

VIII. The appellant's arguments, insofar as they are relevant for the decision, can be summarised as follows:

The analogy between the genomes of the Sendai virus as described in the application as published (see in particular page 5, lines 34 to 37) and of other non-segmented negative sense RNA was established in the prior art as represented by documents D1 (in respect of the measles virus), D2 (in respect of the rabies virus), D7 to D9 and D11 (all four in respect of the paramyxoviruses), as well as D10 (in respect of the filoviridae, paramyxoviridae and rhadboviridae as a whole). Therefore, the skilled person would have been in a position to identify the genes related to the disseminative capability as referred to in claim 1 of the requests on file as well as the genes involved in the viral replication as referred to in the third auxiliary request. Thus, the requests on file met the clarity requirement of Article 84 EPC.

IX. On 19 May 2009 the board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) with an outline of the issues to be discussed at the upcoming oral proceedings. In that communication the view was expressed that the objections raised by the examining division under Article 84 EPC were seen as questioning not only clarity but also the adequacy of the support provided by the description and thus sufficiency of disclosure. The appellant was informed that the board intended to discuss *inter alia* the issue of sufficiency at the oral proceedings. In view of this, in point 11 of the communication the board outlined the main questions to be discussed and provided comments on the issue.

X. On 18 August 2009, in reply to the board's communication, the appellant informed the board that it would not attend the scheduled oral proceedings. No comments and/or further submissions were made on any of the substantive issues referred to in the communication, in particular on the issue of sufficiency of disclosure.

XI. Oral proceedings took place on 18 September 2009 in the absence of the appellant.

XII. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one auxiliary requests 1 to 4 filed with the statement of ground of appeal on 19 February 2008.

Reasons for the Decision

Main request

1. Claim 1 is directed to a complex comprising a viral RNA molecule which is defective in that at least one gene related to the disseminative capability is deleted or inactivated. The description (see application as published), having defined in paragraph [0011] the concept of "disseminative capability", indicates in paragraph [0033] that in the case of the Sendai virus, the genes related to this feature are any one of the M, F, and HN genes. The same paragraph points at the RNA molecule of a Sendai virus Z strain that is deficient only in the M gene as a suitable molecule for the claimed complex.

2. This claim was rejected by the examining division under Article 84 EPC based on the argument that the application "does not provide any guidance as to what genes are to be deleted in viruses other than [the] Sendai virus, except for [the] teaching that these should be genes related to disseminative capability". This was seen by the examining division as a mere formulation of a technical problem, i.e. of a result to be achieved. In their view, the prior art on file did not establish "any relation between the disclosed genes and disseminative capability" and thus the scope of claim 1 could not be clearly delimited (see decision under appeal, pages 3 and 4).

3. Against this rejection, the appellant replied in the statement of grounds of appeal by making reference to documents on file (see D1, D2, D7 and D8) and to new documents (see D9 to D11) which in its view demonstrated that it was clear to a person skilled in the art at the time of filing what was meant by "gene related to the disseminative capability" of a disseminative negative strand virus, and that it was well known in the art that M, F and HN were components necessary for the structure of Sendai virus. It was submitted that a skilled person would have readily understood which genes in other disseminative viruses corresponded to the M, F and HN genes of the Sendai virus.

4. When inviting the appellant to oral proceedings, the board pointed out that in its view the rejection by the examining division under Article 84 EPC was to be seen as also questioning the sufficiency of disclosure under Article 83 EPC. In point 11 of its communication of 19 May 2009, the board indicated that it intended to assess whether the scope of the claims, which extends to all the negative strand RNA viruses (segmented or not and with noticeable variations in their structure), was not broader than would be justified by the extent of the disclosure in the application, account being taken of the fact that the explanations provided in the description and the drawings were only in relation to the *Sendai* virus (a member from one species of the paramyxoviridae which is one of the four families of the non-segmented negative strand RNA viruses). The board further noted that none of the examples seemed to relate to a deletion.

5. As the appellant has chosen not to comment on the aforementioned board's remarks and not to attend the oral proceedings, the board has reviewed the application under the perspective of Article 83 EPC in the light of the comments in the communication. In fact, according to decision G 10/93 (OJ EPO, 1995, 172), in an appeal from a decision of an examining division in which an application was refused, the board has the power to examine whether a requirement of the EPC, which the examining division did not take into consideration in the examination proceedings, is met.

6. No particular non-disseminative complex according to claim 1 is disclosed in the general part of the description or in Examples 1 to 4 (see pages 9 to 12). Indeed, the Sendai virus cDNA used as the starting material for the preparation of the complex of the latter examples is unspecified, as outlined on page 9, paragraph [0041], lines 45 to 52, which indicates that a DNA was constructed by inserting into the pUC18 vector a "Sendai virus cDNA" designed to be transcribed to the negative or positive strand RNA. This disclosure makes the skilled person doubt whether a given gene responsible for the disseminative capability of the viral strain (which one? how?) was deleted or inactivated as required in claim 1. Also the virus strain is not specified. In fact, this disclosure does not exclude that plasmids were used wherein a complete (and active) Sendai virus genome has been inserted, rather than a genome with deletions.

7. No guidance is found also in the two other Examples 5 and 6, as each of them, as explicitly stated on page 9, paragraph [0035], lines 8 to 9, relates to a

disseminative complex rather than a non-disseminative complex as referred to in claim 1.

8. Thus, even for the specific embodiment indicated as being suitable (see point 1 above), the application provides no concrete technical support and thus the burden is left on the skilled person to verify whether the claimed invention can be put into practice in the specific instance and over the whole range of the claim.

9. The written submissions by the appellant in reply to the rejection aimed at demonstrating that the skilled person would have known what the application intends to describe. This might well be so. However, the established case law in relation to Article 83 EPC requires the description to provide more than just an invitation to make experiments in a certain direction based on a sketchy scheme. In order for sufficiency of disclosure to be acknowledged, the skilled reader must be firstly satisfied that the patent specification puts the skilled person in possession of at least one way of putting the claimed invention into practice, and secondly that this can be done over the whole range of the claim. In absence of at least a concrete example like in the present case, already the first requirement is not satisfied.

10. For these reasons, the board concludes that the main request does not comply with Article 83 EPC and cannot be allowed.

Auxiliary requests

11. The reasons outlined above in respect of claim 1 of the main request apply for obvious reasons also to claim 1 of each of the four auxiliary requests. Thus, also these requests do not comply with Article 83 EPC and cannot be allowed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski L. Galligani