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Datasheet for the decision of 4 March 2022

Case Number: T 2764/18 - 3.3.08

Application Number: 09757250.7

Publication Number: 2297309

IPC: C12N7/04, C07K14/18, A61K39/12

Language of the proceedings: EN

Title of invention:
PESTIVIRUS REPLICONS PROVIDING AN RNA-BASED VIRAL VECTOR SYSTEM

Applicant:
Institut für Viruskrankeiten und Immunprophylaxe

Headword:
Pestivirus replicon/INSTITUT FÜR VIRUSKRANKHEITEN

Relevant legal provisions:
EPC Art. 84, 111(1), 123(2)
RPBA 2020 Art. 11, 12(2), 13(2)

Keyword:

Admittance of new main request filed at oral proceedings - (yes)
Added matter - (no)
Clarity - (yes)
Remittal - (yes)

Decisions cited:

G 0009/91, G 0010/91, T 0034/90, T 1966/16, T 0731/17, T 1508/17

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Case Number: T 2764/18 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 4 March 2022

Appellant: (Applicant)	Institut für Viruskrankeiten und Immunprophylaxe Sensemattstrasse 293 3147 Mittelhäusern (CH)
Representative:	Schneiter, Sorin Léman IP Avenue de Riond-Bosson 3 1110 Morges (CH)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 9 July 2018 refusing European patent application No. 09757250.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	B. Stolz
Members:	M. R. Vega Laso
	F. Bostedt

Summary of Facts and Submissions

I. The appeal of the applicant (appellant) lies from a decision of an examining division posted on 9 July 2018, refusing the European patent application No. 09 757 250.7 with the title "Pestivirus replicons providing an RNA-based viral vector system". The application was filed under the Patent Cooperation Treaty and published as WO 2009/146867 (in the following "the application as filed").

II. In the decision under appeal, the examining division found that the amendments introduced into claim 1 according to either the main request or the auxiliary request then on file offended against Article 123(2) EPC. In the examining division's view, there was no basis in the passage on page 12, lines 27 to 29 of the application as filed for broadly combining the use of a particulate delivery vehicle with the protection against RNase degradation. The examining division held that the two features were disclosed as separate alternatives and only in the context of pharmaceutical preparations. Moreover, the application disclosed protection against RNase degradation "*only to be used in certain circumstances*". The examining division thus concluded that the combination of the two features resulted in the creation of subject-matter that goes beyond the content of the application as filed.

III. Together with its statement setting out the grounds of appeal, the appellant filed two sets of claims as main and auxiliary request. These sets of claims were essentially identical to those underlying the decision

under appeal, except that a typographical error was corrected.

IV. The appellant was summoned to oral proceedings. In a communication issued in preparation for the oral proceedings, the board drew the appellant's attention to some issues relating to Articles 123(2) and 84 EPC which appeared to be of particular significance for the decision.

V. In reply to the board's communication, the appellant submitted three sets of claims as new main request and auxiliary requests I and II.

VI. Oral proceedings were held by videoconference on 4 March 2022. During the proceedings, the appellant filed a set of claims that replaced the claims of the main request then on file.

VII. Claim 1 of the present main request reads as follows:

"1. A particulate delivery vehicle comprising an RNA pestivirus replicon lacking essential codons or all codons for one or more structural proteins required for the formation of infectious virus, and carrying a foreign gene, wherein said pestivirus replicon is encapsulated inside the delivery vehicle to enhance protection of the RNA and to deliver the RNA pestivirus replicon to the cytoplasm of mammalian cells for replication and translation of the RNA pestivirus replicon, including said foreign gene, in the cytoplasm."

Dependent claims 2 to 7 and 13 are directed to various embodiments of the particulate delivery vehicle of claim 1. Claims 8 to 12 and 14 relate to pharmaceutical

compositions comprising the claimed particulate delivery vehicle.

VIII. The submissions made by the appellant, as far as they are relevant to the present decision, were essentially as follows:

Admittance of the main request into the proceedings

The new main request should be admitted into the proceedings because the amendments introduced into the claims overcame the objections under Article 123(2) EPC raised for the first time by the board during the oral proceedings, and did not raise any new issues.

Article 123(2) EPC

The subject-matter of the amended claims did not extend beyond the content of the application as filed. Hence, Article 123(2) EPC was not contravened.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the new main request filed during the oral proceedings before the board.

Reasons for the Decision

Admittance of the main request (Article 13(2) RPBA 2020)

1. The set of claims of the present main request was filed during the oral proceedings before the board. Article 13(2) RPBA 2020 is applicable (see Article 25 RPBA 2020).

2. The amendments introduced into the claims are a reaction to issues raised by the board for the first time in a communication sent after notification of a summons to oral proceedings and/or in the oral proceedings. New issues raised by the board at the oral proceedings are regarded as an exceptional circumstance that may justify the admittance of amended claims at such a late stage of the proceedings (Article 13(2) RPBA 2020). The amendments to the claims *prima facie* overcome the objections made by the board and do not give rise to new objections. The board, exercising its discretion, admitted the main request into the proceedings.

Article 123(2) EPC

3. The subject-matter of present claim 1 has a basis in claims 1, 2 and 9 in combination with the disclosure of the description on page 6, lines 26 to 29; page 12, lines 29 to 34; and the paragraph bridging pages 9 and 10 of the application as filed.

4. Claim 9 of the application as filed is directed to a particulate delivery vehicle comprising a pestivirus replicon defined by reference to, *inter alia*, claims 1 and 2. According to claim 1 of the original application, the replicon lacks essential codons for one or more structural proteins required for the formation of infectious virus, and carries a foreign gene; in the embodiment of claim 2, the replicon lacks all codons of those proteins. A replicon for the purpose of the invention is defined on page 6, lines 26 to 29 of the application as filed as an RNA sequence which is derived from a pestivirus and comprises all nucleotides required for replication in cells. Encapsulation of the RNA replicon into the particular

delivery vehicle to enhance protection of the RNA and deliver it to the cells for translation of the RNA into proteins is disclosed on page 12, lines 29 to 34 of the application as filed, which reads:

> "*Alternatively, the pestivirus replicon may be associated with appropriate particulate delivery vehicles.* ***These*** *may enhance protection of the RNA, while also increasing the efficiency for delivery of the RNA to the cells in which the RNA will translate its encoded proteins.* ***To this end****, the RNA is encapsulated into the particulate delivery vehicle during the production of the latter, or is added to the pre-formed particles.*" (emphasis added by the board)

Further, in the paragraph bridging pages 9 and 10 of the application as filed it is disclosed that the replication of the replicon occurs in the cytoplasm of the host cell, and that the translated proteins include the protein(s) encoded by the foreign gene(s).

5. Contrary to the examining division, the board holds that, while the passage quoted above appears in the application in the context of pharmaceutical preparations, it can be derived from the disclosure in the application as a whole that the particulate delivery vehicles of the invention are suitable for use in pharmaceutical preparations, but not necessarily restricted to such a use. See, for instance, claim 9 or the passage on page 4, lines 13 to 16 of the application as filed ("*... that* ***can be used*** *for vaccination ...*", emphasis added).

6. In the decision under appeal, the examining division also held that the passage quoted above disclosed

protection against RNase degradation only under certain circumstances. However, the examining division did not specify any particular circumstances which may limit the use of a particulate delivery vehicle to enhance protection of the RNA pestivirus replicon, and the board is unable to derive any from the passage above.

7. For these reasons, it is concluded that the subject-matter of the amended claim 1 does not extend beyond the content of the application as filed. Hence, the amendments introduced into claim 1 do not offend against Article 123(2) EPC.

8. No issues under Article 123(2) EPC were raised in the decision under appeal with respect to the remaining claims of the main request then on file.

9. The present dependent claim 2 has a basis in, *inter alia*, claim 8 and page 6, lines 21 to 24 of the application as filed.

10. The features of the particulate delivery vehicle specified in dependent claim 3 can be derived from the passage on page 9, lines 6 to 12 of the application as filed. As apparent from page 1, lines 28 to 32 of the application, besides the ability to inhibit type I interferon induction, the N^{pro} gene product has an autoproteolytic function which, as is derivable from page 9, lines 10 to 12 ("*... without modifying other functions of the N^{pro} gene product*"), is maintained in the N^{pro} mutants C112R and/or C136N.

11. The basis for dependent claims 4 and 5 is found on page 13, lines 1 and 2, and lines 7 and 8, respectively.

12. The features specified in dependent claim 6 are based on Figures 2C and 2E, as well as on the disclosure on page 3, lines 29 to 32; and page 5, lines 20 to 23 of the application as filed. The presence of a stop codon is regarded as implicit in the disclosure of a bicistronic construct.

13. It is disclosed in the passage on page 10, lines 23 and 24 of the application as filed that, in addition to the sequence encoding one or all viral structural proteins, cytopathogenic replicons lack the non-structural proteins p7 and NS2. It is implicit in this disclosure that a replicon comprising a p7 gene is non-cytopathogenic. Hence, the subject-matter of dependent claim 7 is disclosed in the application as filed.

14. Present claims 8 to 12 and 14 are directed to pharmaceutical compositions comprising the particulate delivery vehicle of the invention. Such pharmaceutical compositions are disclosed in claim 11 and the passage from page 12, line 20 to page 15, line 2, in particular page 13, lines 30 and 31 of the application as filed. It is derivable from page 4, lines 18 to 24 of the application as filed that the pharmaceutical composition of the invention may be a vaccine, and that the foreign gene incorporated into the replicon may encode a gene product for immunizing against an infectious agent. Pharmaceutical compositions of the invention, for oral, nasal or buccal administration are disclosed on page 12, lines 22 and 23 of the application as filed, and administration to a human is derivable from the passage on page 1, lines 7 to 10. Finally, a particulate delivery vehicle and a pharmaceutical composition for use in gene therapy in

mammals are disclosed on page 1, lines 7 to 10 and page 4, lines 13 to 16.

15. Hence, the board concludes that the amendments introduced into the claims do not contravene Article 123(2) EPC.

Article 84 EPC

16. In the decision under appeal, the examining division did not raise any objection concerning clarity or support in the description with respect to the claims of the main request then on file. It is however apparent from the communications issued during the examination proceedings that there were some concerns with respect to the clarity of the wording "*lacking* ***essential*** *codons* [...] *for one or more structural proteins required for the formation of infectious virus*" (emphasis added).

17. This wording appears also in present claim 1. The board has no doubt that a person skilled in the art reading the wording quoted in the preceding paragraph understands that essential codons of one or more structural proteins within the meaning of claim 1 are those codons, in the absence of which one or more structural proteins are not functional, the virus thus becoming non-infectious. This is supported by the disclosure in the passage bridging pages 7 and 8 of the application as filed (see, in particular, page 8, lines 2 to 4).

18. Hence, the board is satisfied that the requirements of Article 84 EPC are met.

Remittal to the examining division (Article 111(1) EPC)

19. The present application was refused solely on the grounds of added matter. Thus, the examining division did not take an appealable decision on the compliance of the application with the requirements of Articles 83, 54 and 56 EPC.

20. Having found that the sole ground for refusal of the application is not justified in view of the amendments introduced into the set of claims filed as main request in appeal proceedings, the board may proceed further with the examination of the application, in particular with regard to Articles 83, 54 and 56 EPC, or remit the case to the examining division for further prosecution (Article 111(1) EPC).

21. Since the present appeal was pending on 1 January 2020, Article 11 RPBA 2020 is applicable. This article provides that the board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

22. It has been established in numerous decisions of the Boards of Appeal (see, *inter alia*, decisions G 9/91, OJ EPO 1993, 408; G 10/91, OJ EPO 1993, 420; and T 34/90, OJ EPO 1992, 454) that the primary function of the appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a department of the European Patent Office. This is recalled in Article 12(2) RPBA 2020 which applies also to the present case.

23. Conducting a complete examination of the application for compliance with the requirements of Articles 83, 54

and 56 EPC, for which in the present case no decision of the examining division exists yet, would run contrary to the primary object of the appeal proceedings which is to review the decision under appeal in a judicial manner. In line with decisions T 1966/16 of 20 January 2020, T 731/17 Of 15 January 2020, and T 1508/17 of 31 January 2020, the board holds that this circumstance presents itself as a special reason for remittal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of claims 1 to 14 of the main request filed at the oral proceedings before the board.

The Registrar: The Chairman:

M. Schalow B. Stolz

Decision electronically authenticated