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D E C I S I O N
of 14 September 2005

Case Number: T 1231/01 - 3.3.4

Application Number: 93203042.2

Publication Number: 0595436

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Language of the proceedings: EN

Title of invention:
Porcine respiratory and reproductive disease virus, vaccines and viral DNA

Applicants:
SOLVAY ANIMAL HEALTH, INC.
IOWA STATE UNIVERSITY RESEARCH FOUNDATION, INC.

Headword:
Porcine virus/SOLVAY

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
EPC R. 28

Keyword:
"Added subject-matter (no)"
"Sufficiency of disclosure, novelty, inventive step (yes)"

Decisions cited:
T 0464/94, T 0737/96

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1231/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 14 September 2005

Appellants: SOLVAY ANIMAL HEALTH, INC.
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and

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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 16 May 2001 refusing European application No. 93203042.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
G. Weiss

Summary of Facts and Submissions

I. The appeal was lodged by the Applicants (Appellants) against the decision of the Examining Division to refuse under Article 97(1) EPC the European patent application 93203042.2, publication number 595 436. The application claims priority from US 969 071; 30 October 1992 and US 131 625; 5 October 1993 and has the title: "Porcine respiratory and reproductive disease virus, vaccines and viral DNA".

II. The Examining Division decided that claims 1, 2, 4, 5 and 16 of the only request before them had been amended in such a way that it contained subject-matter extending beyond the content of the application as filed and thus contravened the requirements of Article 123(2) EPC).

III. The Board issued communications on 12 February 2004, on 28 June 2004, on 10 December 2004 and on 7 April 2005.

IV. The Appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 13 of the new main request filed on 23 August 2005. These claims correspond to claims 1 to 13 which have been filed on 5 August 2005 as second auxiliary request.

V. Claim 1 of the new main request reads:

"A naturally occurring isolated virus which causes porcine reproductive and respiratory syndrome (PRRS), selected from the group consisting of the viruses

deposited at the American Type Culture Collection under the accession numbers VR 2385 and VR 2386."

Claim 2 refers to a composition containing the virus of claim 1, claims 3 and 4 to a vaccine containing an inactivated or attenuated form of the virus. Claims 5 to 7 relate to a method for producing the vaccine. Claim 8 refers to a kit containing an antibody directed to the virus. Claims 9 to 11 refer to polynucleotides isolated from the virus and to proteins encoded by them. Claims 12 and 13 relate to a method for culturing the virus.

VI. The Appellants argued that the claims of the new main request were in accordance with the requirements of Article 123(2) EPC. Their subject-matter was not disclosed in the prior art documents on file and could not be derived in an obvious way from these documents either when taken alone or in any combination (Articles 54 and 56 EPC).

VII. The following documents are referred to in this decision:

(1) American Journal of Veterinary Research, vol.53, April 1992, pages 485 to 488

(2) The Veterinary Quarterly, vol.13, 1991, pages 121 to 130

(3) WO-92/21 375, publication date 10 December 1992

(5) WO-93/07 898, publication date 29 April 1993

(6) Virology, vol.193, March 1993, pages 329 to 339

Reasons for the decision

1. Claim 1 is based on page 25, lines 8 to 15, and claim 2 on page 25, lines 24 to 29 of the application as originally filed. Claim 3 finds a basis on page 5, lines 17 to 20 and on page 15, lines 27 to 29 as filed. Claim 4 is based on page 26, lines 11 to 12. Claims 5 to 7 correspond to original claims 14 to 16. Claim 8 is based on original claim 19 and page 34, line 31 to page 35, line 1 as filed. Claims 9 to 12 are based on original claims 22, 23 and 26 and on pages 2 to 7 and 9 to 12 of the sequence listing as originally filed. Claims 12 and 13 are derived from original claims 27 and 28, wherein the designation PSP-36-SAH has been replaced by the deposit accession number ATCC CRL 11171, as disclosed on page 31, lines 6 to 11 as originally filed.

   Claims 1 to 13 of the new main request meet the requirements of Article 123(2) EPC.

2. The claims are clear, precise and supported by the description, as required by Article 84 EPC.

3. The two viruses according to claim 1 have been deposited by the Appellants under the terms of the Budapest Treaty. The deposits were received on 30 October 1992 by the International Depository Authority, the American Type Culture Collection, as can be seen from the deposit receipt dated 12 November 1992, that has been submitted by the Appellants with a letter

dated 5 August 1994. The deposit numbers, VR 2385 (ISU-12-SAH, plaque purified) and VR 2386 (ISU-12, not plaque purified), are contained in the application as originally filed (page 25, lines 8 to 15).

Thus the requirements of Article 83 EPC, sufficiency of disclosure, in combination with Rule 28 EPC are met.

4. Document (1) refers to the experimental reproduction of swine infertility and respiratory syndrome (SIRS) in pregnant sows. It reports the inoculation of sows with lung homogenates from clinically affected pigs and with a virus, deposited under the number ATCC VR-2332, isolated in cell culture from the lung homogenate. Six out of nine infected sows developed neutralizing antibodies. The virus isolate ATCC VR-2332 was found to cause the reproductive failure associated with SIRS (see summary and discussion). The document does not disclose the nucleotide sequence of the isolated virus.

Document (2) discloses the isolation of the so-called Lelystad virus, the etiological agent of the mystery swine disease in the Netherlands. The virus was isolated from clinically affected piglets and sows. Antibodies directed against the virus were also found in pigs with mystery swine disease in England, Germany and the United States. Infection with Lelystad virus was found to be the likely cause of mystery swine disease (see summary and discussion). Document (2) does not disclose the nucleotide sequence of the Lelystad virus.

5. Figure 19 of the present application discloses the 1938 bp 3'-terminal sequence of the virus of claim 1 (SEQ ID NO 8).

In the light of missing sequence data in documents (1) and (2) an objection because lack of novelty (Article 54 EPC) of the virus isolates of claim 1 could be raised on the basis of probability only.

According to the case law of the Boards of Appeal it is not justifiable to decide whether a document is prejudicial to novelty on the **basis of probability**. In order to decide that the subject-matter of a claim lacks novelty, the department concerned, having taken all facts and arguments put forward during the proceedings into consideration, has to be **sure** that the decision is justified (cf decision T 464/94 of 21 May 1997; point (16) of the reasons).

6. Moreover, the virus isolates of claim 1 are distinguished from the viruses disclosed in documents (1) and (2) by their nucleotide sequence. This can be seen from a comparison between SEQ ID NO 8 of the present application, disclosing the 1938 bp 3'-terminal sequence of the virus of claim 1 and figure 5 of document (6), showing the sequence of VR 2332, and figure 1 of document (3), disclosing the sequence of the Lelystad virus (strain CNCM I-1102).

Document (5) relates to another viral strain, CNCM I-1140, without disclosing its sequence.

Documents (3), (5) and (6) have been published between the two priority dates claimed by the present application.

7. Therefore, the subject-matter of claim 1, namely two isolated, deposited viruses, is novel. The same applies to the subject-matter of claims 2 to 13, referring to compositions and vaccines comprising it, to methods for producing and culturing it, to polynucleotides isolated from it and proteins encoded therefrom and to kits comprising an antibody directed to it.

The requirements of Article 54 EPC are met.

8. In accordance with the problem and solution approach, the Boards of Appeal in their case law have developed certain criteria for identifying the closest prior art providing the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Edition 2001, chapter I.D.3.1).

The present application serves the purpose to provide an isolated virus causing PRRS, a vaccine containing it and a diagnostic kit comprising an antibody directed to it.

9. In the light of the criteria for identifying the closest state of the art either a document referring to strain VR 2332, like document (1), or to the Lelystad virus, as document(2), is considered to be the most appropriate starting point for the objective assessment of an inventive step following the problem and solution approach.

Accordingly, the problem underlying the present application is seen in the provision of a further, alternative strain causing PRRS, which can be used in a vaccine to protect pigs against this disease.

It has been convincingly shown in example VIII on page 41 (see also figure 34) that the highly virulent isolates according to claim 1 can efficaciously be used as vaccines against PRRS.

10. Document (2), reporting the isolation of the Lelystad virus, in the last sentence on page 129, comes to the conclusion that *"[f]inally, research can now begin on developing a vaccine against MSD."*

Neither document (2) nor any other prior art document on file contains technical information concerning the experimental design or structure of such research program that would enable a skilled person to arrive at the subject-matter of claim 1 in an obvious way.

11. The isolation of a specific virus strain useful for a defined purpose, here as vaccine component to protect animals against PRRS, is a technique of random nature. The skilled person trying to solve this problem, having from nil to high expectations, has to expect a large

number of failed attempts. In such technical circumstances, it is the **actual isolation** of a virus indeed having the desired characteristics which is surprising. The Board comes to the decision that the isolation of the specific viruses of claim 1, which can efficaciously be used as vaccines against PRRS, contains elements of surprise which justify the recognition of an inventive step (cf decision T 737/96 of 9 March 2000; point (17) of the reasons).

The subject-matter of claim 1, as well of claims 2 to 13, meets the requirements of Article 56 EPC.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 13 of the new main request, filed on 23 August 2005, and a description adapted thereto.

Registrar: Chair:

P. Cremona U. Kinkeldey