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**Datasheet for the decision
of 12 April 2018**

Case Number: T 1123/13 - 3.3.04

Application Number: 04801973.1

Publication Number: 1651263

IPC: A61K39/12, A61K39/295,
C07K14/18

Language of the proceedings: EN

Title of invention:
Safe mutant viral vaccines

Patent Proprietor:
Zoetis Services LLC

Opponent:
Boehringer Ingelheim Vetmedica GmbH

Headword:
Viral vaccines/ZOETIS

Relevant legal provisions:
EPC Art. 114(2), 123(3)
RPBA Art. 13(1)

Keyword:

Late-filed main request - admitted (no)

Auxiliary requests 1 to 15 - extension of scope of protection
(yes)

Late-filed auxiliary requests 16 to 19 and 21 to 23 - admitted
(no)

Decisions cited:

Catchword:

-



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Case Number: T 1123/13 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 12 April 2018

Appellant I: Zoetis Services LLC
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 February 2013 concerning maintenance of the
European Patent No. 1651263 in amended form.**

Composition of the Board:

Chairwoman R. Morawetz
Members: B. Claes
M. Blasi

Summary of Facts and Submissions

I. The appeals of the patent proprietor (hereinafter "appellant I") and the opponent (hereinafter "appellant II") lie against the interlocutory decision of the opposition division maintaining European patent No. 1 651 263, entitled "*Safe mutant viral vaccines*" in amended form.

Independent claim 1 and dependent claims 2 to 4 of the patent as granted read:

"1. A vaccine composition comprising at least two live mutant viruses of the same family, wherein each virus contains a mutation in the viral genome, and the mutations in the viruses reside in the same genomic site such that the mutant viruses cannot recombine with each other to eliminate the mutations, and wherein two of the live mutant viruses consist of mutant Bovine Viral Diarrhea Viruses (BVDV).

2. The vaccine composition of claim 1, wherein the two mutant live viruses consist of a mutant Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a mutant Bovine Viral Diarrhea Virus Type 2 (BVDV-2).

3. The vaccine composition of claim 2, wherein the two mutant live viruses consist of a cytopathic (cp) BVDV-1 and a cp BVDV-2, and are both attenuated.

4. The vaccine composition of claim 3, wherein the cp BVDV-1 and the cp BVDV-2 both comprise a mutation in the NS2-3 region that results in a cytopathic biotype."

Independent claim 8 of the patent as granted read:

"8. A method of preparing a safe viral vaccine comprising selecting or constructing two live mutant viruses of the same family, wherein each virus contains a mutation and the mutations in the viruses reside in the same genomic site such that the mutant viruses can not undergo homologous recombination to eliminate the mutations, and wherein the viruses consist of mutant BVDV."

- II. The patent was opposed on the grounds in Article 100(a) EPC, namely lack of novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and Article 100(c) EPC. In the decision under appeal the opposition division held that claim 1 of the main request, filed with a letter of 21 December 2012, met the requirements of Rule 80 and Article 123(2) and (3) EPC but lacked clarity (Article 84 EPC). The first auxiliary request, filed during the oral proceedings on 23 January 2013, was found to fulfill the requirements of the EPC.

Claim 1 of the first auxiliary request read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation in the NS2-3 region that results in the cytopathic biotype such that the two mutant viruses cannot recombine with each other to eliminate the mutations, and are both attenuated."

- III. With its statement of grounds of appeal appellant I re-submitted the claims of the main request, submitted sets of claims as first to seventh auxiliary requests,

the third of which was identical to the first auxiliary request addressed in the impugned decision, and argued that the claims of the main request complied with the requirements of Article 84 EPC.

Claim 1 of the **first auxiliary request** read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation that confers the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot recombine with each other to eliminate the mutations."

Claim 1 of the **second auxiliary request** read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation in the NS2-3 region that results in the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot recombine with each other to eliminate the mutations, and are both attenuated." (emphasis added by the board)

Claim 1 of the **third auxiliary request** was identical to claim 1 of the first auxiliary request considered by the opposition division (see section II) and was identical to claim 1 of the second auxiliary request but for the absence of the wording underlined above.

Claim 1 of the **fourth auxiliary request** read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a heterologous sequence insertion in the NS2-3 region that results in the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot recombine with each other to eliminate the mutations, and are both attenuated." (emphasis added by the board)

Claim 1 of the **fifth auxiliary request** was identical to claim 1 of the fourth auxiliary request but for the absence of the wording underlined above.

Claim 1 of the **sixth auxiliary request** read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation associated with the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot recombine with each other to eliminate the mutations, wherein the two mutant live viruses are both attenuated, and wherein the cp BVDV-1 and the cp BVDV-2 both comprise a mutation in the NS2-3 region that results in a cytopathic biotype." (emphasis added by the board)

Claim 1 of the **seventh auxiliary request** was identical to claim 1 of the sixth auxiliary request but for the absence of the wording underlined above.

IV. In its statement of grounds of appeal, appellant II argued, *inter alia*, that claim 1 of the main request and of the first auxiliary request addressed in the proceedings before the opposition division did not comply with the requirements of Article 123(3) EPC (cf. pages 6 to 19 of appellant II's statement of grounds of appeal).

V. In its reply to appellant II's appeal, appellant I argued, *inter alia*, that claim 1 of the main request complied with the requirements of Article 123(3) EPC and submitted further auxiliary requests 8 to 15.

Claim 1 of the **eighth auxiliary request** read:

"1. A vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation associated with the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot homologously recombine with each other to eliminate the mutations." (emphasis added by the board)

Claim 1 of each of the **ninth to fifteenth auxiliary requests** was identical to claim 1 of the first to seventh auxiliary requests (see section III), respectively, but for having the word "homologously" inserted in between the words "cannot" and "recombine".

VI. In its reply to appellant I's appeal, appellant II, *inter alia*, extended its objections under Article 123(3) EPC to claim 1 of auxiliary requests 1 to 7.

- VII. After having summoned the parties to oral proceedings, the board informed them of its preliminary assessment of their requests and of certain substantive and legal matters concerning the appeal in a communication pursuant to Article 15(1) RPBA dated 23 January 2018. The board, *inter alia*, expressed its preliminary opinion that claim 1 of the main request did not comply with the requirements of Article 123(3) EPC.
- VIII. In further letters, both appellants submitted additional arguments relating, *inter alia*, to the compliance of claim 1 of the main request with the requirements of Article 123(3) EPC. With a letter dated 15 March 2018 appellant I filed auxiliary requests 16 to 19.

Claim 1 of **auxiliary request 16** read:

"1. A vaccine composition comprising at least two live mutant viruses of the same family, wherein each virus contains a mutation in the viral genome, and the mutations in the viruses reside in the same genomic site such that the mutant viruses cannot recombine with each other to eliminate the mutations, and wherein two of the live mutant viruses consist of mutant Bovine Viral Diarrhea Viruses (BVDV), wherein the two mutant live viruses consist of a mutant cytopathic (cp) Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a mutant cp Bovine Viral Diarrhea Virus Type 2 (BVDV-2), and are both attenuated, and wherein the cp BVDV-1 and the cp BVDV-2 both comprise a mutation in the NS2-3 region that results in a cytopathic biotype." (emphasis added by the board)

Claim 1 of **auxiliary request 17** was identical to that of auxiliary request 16 but for the absence of the wording underlined above.

Claim 1 of **auxiliary request 18** read:

"1. A vaccine composition comprising at least two live mutant viruses of the same family, wherein each virus contains a mutation in the viral genome, and the mutations in the viruses reside in the same genomic site such that the mutant viruses cannot recombine with each other to eliminate the mutations, and wherein two of the live mutant viruses consist of mutant Bovine Viral Diarrhea Viruses (BVDV), wherein the two mutant live viruses consist of a mutant cytopathic (cp) Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a mutant cp Bovine Viral Diarrhea Virus Type 2 (BVDV-2), and are both attenuated, and wherein the cp BVDV-1 and the cp BVDV-2 both comprise a heterologous sequence insertion in the NS2-3 region that results in a cytopathic biotype." (emphasis added by the board)

Claim 1 of **auxiliary request 19** was identical to that of auxiliary request 18 but for the absence of the wording underlined above.

- IX. During the oral proceedings appellant I filed new, and withdrew the earlier, main requests three times and further filed auxiliary requests 21 to 23. At the end of the oral proceedings the chairwoman announced the decision of the board.

The final wording of claim 1 of the **main request** read:

"1. A vaccine composition comprising at least two live mutant viruses of the same family, wherein each virus contains a mutation in the NS2-3 region that results in the cytopathic biotype which resides in the same genomic site such that the two mutant viruses cannot recombine with each other to eliminate the mutations, and are both attenuated, wherein two of the live mutant viruses consist of a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2)." (emphasis added by the board)

Claims 1 of **auxiliary requests 21 and 23** were identical to claims 1 of auxiliary requests 16 and 17, respectively (see section VIII). Claim 1 of auxiliary request 22 was identical to claim 1 of auxiliary request 17 except that the wording "in the NS2-3 region" had been deleted.

- X. The arguments of appellant I, in so far as they are relevant for the decision, can be summarised as follows:

First to fifteenth auxiliary requests - claim 1 - requirements of Article 123(3) EPC

Both the vaccine of the claims as granted and the vaccine of claim 1 could "comprise" more than the live mutant viruses of the same family because the open language "comprising" was present in claim 1 as granted and in claim 1 of each of the first to fifteenth auxiliary requests. Claim 1 required that "each virus" in the claimed composition contain the mutation. There was no reason to assume that "each" referred only to

the two recited viruses and not to any other virus potentially present in the composition that could recombine with another virus in the composition to eliminate the mutations.

It was a misreading of the claim, with a mind desirous of misunderstanding, to assume that a third or further virus could be present in the composition that could counteract the gist of the invention, i.e. avoiding recombination that eliminates the mutation. Such embodiments were not envisaged by the person skilled in the art.

Thus claim 1 did not encompass embodiments that were not within the scope of the claims as granted and therefore complied with Article 123(3) EPC.

Main request and auxiliary requests 16 to 19 and 21 to 23 - admission into the appeal proceedings

Claim 1 of the **main request** resulted from a combination of claim 1 as granted and claim 1 of the third auxiliary request. It had been filed in response to the opinion of the board that the earlier versions of the main request and first to fifteenth auxiliary requests failed to comply with the requirements of Article 123(3) EPC, which had come as a surprise to appellant I.

Even if the main request had been filed at an earlier stage of the appeal proceedings, the board would still have had to deal with it. Also, this request neither made the appeal proceedings more complex nor delayed them.

Auxiliary requests 16 to 19 had been filed in writing in response to the preliminary opinion first expressed by the board in the communication that claim 1 of the then pending main request did not comply with the requirements of Article 123(3) EPC. It had only been on receipt of the board's communication that appellant I had learned that there might be an issue of non-compliance with Article 123(3) EPC. Auxiliary requests 16 to 19 had been presented at the earliest possible point in time. The claims closely resembled the wording of the granted claims and should therefore not come as a surprise to appellant II. Moreover, the amendments were straightforward.

Auxiliary requests 21 to 23 (and auxiliary request 20, which was later withdrawn) had been filed at the start of the oral proceedings. Auxiliary requests 21 and 23 were identical to auxiliary requests 16 and 17, respectively. Auxiliary request 22 was based on auxiliary request 17. These requests resolved all issues raised in the appeal proceedings and should thus be admitted into the proceedings.

XI. The arguments of appellant II, in so far as they are relevant for the decision, can be summarised as follows:

First to fifteenth auxiliary requests - claim 1 - requirements of Article 123(3) EPC

Claim 1 as granted defined a vaccine composition comprising at least two live mutant viruses of the same family, wherein each virus of these viruses contained a mutation such that the two mutant viruses could not recombine with each other to eliminate the mutations. The term "comprising" allowed the claimed vaccine

composition to contain more than the two specific BVDV viruses mentioned in the claim and - if present - such viruses might or might not belong to the same family, i.e. the *Flaviviridea*. Claim 1 as granted required, however, that all the life mutant viruses belonging to the same family and present in the vaccine composition contained a mutation such that they could not recombine with each other to eliminate the mutations.

Claim 1 of the auxiliary requests required that the claimed vaccine composition "comprise" a particular BVDV-1 and a BVDV-2 virus and also allowed embodiments wherein more than these two minimum mutant viruses of the same family might be present, e.g. a third or fourth mutant virus of the *Flaviviridea* family. The claim provided that the mutations were "such that the two mutant viruses" could not recombine with each other to eliminate the mutations. The claim, however, did not require that a possible third or fourth mutant virus of the same family have the same limiting feature.

These conceptual embodiments were outside the scope of the granted claims. The amendment thus resulted in an extension of the scope of protection contrary to the requirements of Article 123(3) EPC.

Main request and auxiliary requests 16 to 19 and 21 to 23 - admission into the appeal proceedings

The **main request** was late filed since the issue of Article 123(3) EPC had been present in the appeal proceedings from the outset. The request did not solve all the issues but rather raised new ones. Claim 1 still required the feature "such that the two mutant viruses" could not recombine with each other to eliminate the mutations. Accordingly, for the same

reasons as claim 1 of each of the first to fifteenth auxiliary requests, the claim did not comply with the requirements of Article 123(3) EPC. The request should therefore not be admitted into the appeal proceedings.

Auxiliary requests 16 to 19 had not been filed in response to appellant II's appeal and were thus late filed. Claim 1 of these requests did not converge with claim 1 of the higher-ranking auxiliary requests. Rather, the wording of claim 1 reverted to wording close to that of claim 1 of the patent as granted. The request should therefore not be admitted into the appeal proceedings.

Auxiliary requests 21 to 23 were identical to and/or based on auxiliary requests 16 and 17. They had been filed only during the oral proceedings, i.e. even later than auxiliary requests 16 to 19. Thus, for the same reasons, they should not be admitted into the appeal proceedings.

XII. The requests of the parties were the following:

Appellant I requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of one of the following requests:

new main request filed at the oral proceedings before the board,

auxiliary requests 1 to 7 filed with the statement of grounds of appeal,

auxiliary requests 8 to 15 filed with the reply to appellant II's appeal,

auxiliary requests 16 to 19 filed with the letter of 15 March 2018,

auxiliary requests 21 to 23 filed at the oral proceedings before the board.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked in its entirety. The new main request and auxiliary requests 1, 2, 4 to 19 and 21 to 23 should not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeals are both admissible.

First to fifteenth auxiliary requests - claim 1 - requirements of Article 123(3) EPC

2. The first to fifteenth auxiliary requests had all been filed by appellant I before expiry of the time limit for replying to appellant II's appeal. In relation to some of these auxiliary requests, appellant II had requested that they not be taken into consideration by the board pursuant to Article 12(4) RPBA. The board considered the substance of all these claim requests and, in the present circumstances, sees no need to provide further justification for having done so.
3. Claim 1 of each of the first to the fifteenth auxiliary requests is for "a vaccine composition comprising a live cytopathic Bovine Viral Diarrhea Virus Type 1 (BVDV-1) and a live cytopathic Bovine Viral Diarrhea Virus Type 2 (BVDV-2) wherein each virus contains a mutation (...) such that the two mutant viruses cannot (...) recombine with each other to eliminate the mutations."

4. The claimed vaccine composition is not, however, limited to containing only the two defined live mutant BVDV-1 and BVDV-1 viruses each having a mutation such that the two mutant viruses cannot recombine with each other to eliminate the mutations. Indeed, the wording "comprising" means that vaccine compositions which contain, in addition to these two defined live mutant BVDV-1 and BVDV-1 viruses having the defined mutation, further live mutant viruses - which belong either to the same family of viruses as the BVDV, i.e. the *Flaviviridea*, or to another - also constitute subject-matter on which the claim reads. The wording of the claim, however, does not require that these further live mutant viruses, including those belonging to the *Flaviviridea* family, have a particular mutation, let alone have a mutation such that the mutant virus cannot recombine with other viruses present in the composition to eliminate their mutations.

5. Claim 1 as granted (see section I), however, required that the claimed vaccine composition "compris[e] at least two live mutant viruses of the same family, wherein each virus contains a mutation ... such that the mutant viruses cannot recombine with each other to eliminate the mutations, and wherein two of the live mutant viruses consist of mutant Bovine Viral Diarrhea Viruses (BVDV)" (emphasis added by the board).

6. Claim 1 as granted thus required that each virus contained in the claimed vaccine composition and belonging to the same family as the two BVDV viruses present, i.e. the *Flaviviridea*, contain a mutation such that the mutant viruses cannot recombine with each other to eliminate the mutations. Claim 1 as granted thus excluded from its subject-matter vaccine compositions in which further live mutant viruses

belonging to the *Flaviviridea* are present which lack a mutation such that the mutant virus cannot recombine with other viruses present in the composition to eliminate the mutations.

7. The board notes that claim 1 of each of the first to fifteenth auxiliary requests is an amended form of claim 1 as granted and so has to be examined for compliance with the requirements of Article 123(3) EPC. In this respect the board considers, contrary to appellant I, that the above construction of claim 1 of each of the first to fifteenth auxiliary requests amounts to an objective reading of the claim through the eyes of the skilled person considering it with a mind willing to understand rather than one desirous of misunderstanding. In the context of the requirements of Article 123(3) EPC a finding that an amended claim confronts the skilled person with subject-matter which was not protected by the corresponding claim as granted can only result in a finding that the scope of protection has been extended.
8. In the present case, claim 1 of each of the first to fifteenth auxiliary requests covers vaccine compositions which were not covered by claim 1 as granted.
9. Claim 8, the sole other independent claim granted (see section I), is for a method of preparing a safe viral vaccine which cannot result in product protection for the vaccine compositions as defined in claim 1 of the first to the fifteenth auxiliary request either.
10. In view of the above considerations, claim 1 of each of the first to fifteenth auxiliary requests does not comply with the requirements of Article 123(3) EPC.

*Main request and auxiliary requests 16 to 19 and 21 to 23 -
admission into the appeal proceedings*

Main request

11. Appellant I filed the final new **main request** (see section IX) at the end of the oral proceedings, after the board had heard the parties on three earlier versions of a main request, which had all subsequently been withdrawn.
12. The board notes that the **main request** was not filed with appellant I's statement of grounds of appeal or with its reply to the appeal of appellant II, although the issue of Article 123(3) EPC had been addressed in the decision under appeal and, in detail, in appellant II's statement of grounds of appeal. Nor was it filed in direct response to the board's communication pursuant to Article 15(1) RPBA giving its preliminary opinion on this issue.
13. The board furthermore notes that, as pointed out by appellant II, claim 1 still required merely that the mutation be "such that the two mutant viruses" could not recombine with each other to eliminate the mutations. Accordingly, for the same reasons as claim 1 of each of the first to fifteenth auxiliary requests, the claim did not comply with the requirements of Article 123(3) EPC (see points 3 to 10, above). Thus, the main request did not overcome the issue of extension of the scope of protection and, for this reason alone, was clearly unallowable.
14. Accordingly, the board, exercising its discretion pursuant to Article 114(2) EPC, governed by the principles laid down in Article 13(1) RPBA, decided not

to admit the appellant I's main request into the appeal proceedings.

Auxiliary requests 16 to 19 and 21 to 23

15. **Auxiliary requests 16 to 19** were not filed either with appellant I's statement of grounds of appeal or with its reply to the appeal of appellant II although the issue of Article 123(3) EPC had been addressed in the decision under appeal and, in detail, in appellant II's statement of grounds of appeal. They had been filed only one month before the oral proceedings were due to take place, in response to the board's communication pursuant to Article 15(1) RPBA giving its preliminary opinion on this issue.
16. Appellant I justified filing these requests late by referring to the preliminary opinion expressed by the board in its communication. This opinion had come as a surprise. The board, however, notes that this preliminary opinion, rather than constituting a surprising turn of events, was merely based on arguments filed by appellant II with its statement of grounds of appeal. Accordingly, the board considers that, if they were considered by appellant I to remedy the issues under Article 123(3) EPC, the proper point in time for filing these requests was its reply to appellant II's appeal.
17. Furthermore, the wording of claim 1 of these requests is, as compared to the first to fifteenth auxiliary requests, again closer to the wording of claim 1 as granted (see section VIII), albeit amended by the inclusion of further features and a change of wording. Claims based on the wording of claim 1 as granted had not been pursued by appellant I in the opposition

proceedings. Accordingly, these claim requests do not converge with higher-ranking auxiliary requests but constitute a fresh case with the potential to raise further issues and generate further objections from appellant II.

18. Accordingly, the board, exercising its discretion pursuant to Article 114(2) EPC, governed by the principles laid down in Article 13(1) RPBA, decided also not to admit auxiliary requests 16 to 19 into the appeal proceedings.

19. **Auxiliary requests 21 to 23** are identical to or based on auxiliary requests 16 and 17, but filed at a yet later stage in the proceedings, so the board decided, for the same reasons as for the latter two, not to admit them into the appeal proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



P. Cremona

R. Morawetz

Decision electronically authenticated