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Datasheet for the decision of 21 March 2023

Case Number: T 1289/21 - 3.3.08

Application Number: 15162413.7

Publication Number: 2992897

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A61K39/12, C12N7/00, A61K35/74

Language of the proceedings: EN

Title of invention:

Immunogenic compositions comprising Lawsonia intercellularis

Patent Proprietor:

Boehringer Ingelheim Animal Health USA Inc.

Opponents:

Intervet International B.V. (Opposition withdrawn) Ceva Santé Animale

Headword:

Immunogenic compositions comprising L. intercellularis/BOEHRINGER INGELHEIM

Relevant legal provisions:

EPC Art. 76(1), 100(c)

Keyword:

Grounds for opposition - added subject-matter (yes)
Divisional application - subject-matter extends beyond content
of earlier application (yes)

Decisions cited:

G 0002/10, T 0012/81, T 0783/09, T 1852/11, T 0305/13, T 1525/17



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Case Number: T 1289/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 21 March 2023

Appellant: Boehringer Ingelheim Animal Health USA Inc.

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- opposition withdrawn -

Representative: Intervet International B.V.

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Respondent: Ceva Santé Animale

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 31 May 2021 revoking European patent No. 2992897 pursuant to

Article 101(2) and Article 101(3)(b) EPC

Composition of the Board:

M. Blasi

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Summary of Facts and Submissions

I. The patent proprietor's (appellant's) appeal lies from the opposition division's decision to revoke European patent No. 2 992 897 (hereinafter "the patent").

Claim 1 of the patent reads as follows:

- "1. A combination vaccine comprising
- i) L. intracellularis antigen effective for reducing the incidence of or lessening the severity of porcine proliferative enteropathy (PPE) caused by Lawsonia intracellularis, wherein the L. intracellularis antigen is killed L. intracellularis, and
- ii) immunological active components of M. hyopneumoniae and Porcine circovirus effective for the treatment and/ or prophylaxis of infections caused by M. hyopneumoniae and Porcine circovirus, wherein the immunological active component of M. hyopneumoniae is killed M. hyopneumoniae."
- II. The patent entitled "Immunogenic compositions comprising Lawsonia intercellularis [sic]" was granted on European patent application No. 15 162 413.7 (hereinafter "the application"), which is a divisional application in respect of European patent application No. 06 738 652.4, which had been filed as an international patent application published as WO 2006/099561 (hereinafter "the earlier application").
- III. Two oppositions were filed against the patent. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC. Opponent 1 withdrew the

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opposition during the opposition proceedings and ceased to be a party to the proceedings.

- IV. In the decision under appeal, the opposition division considered a main request (patent as granted) and sets of claims of 12 auxiliary requests. It held that claim 1 of the patent as granted contained subjectmatter which extended beyond the content of the earlier application as filed (Article 100(c) EPC) and that the same applied to claim 1 of each of auxiliary requests 1 to 12 (Article 76(1) EPC).
- V. With the statement of grounds of appeal, the appellant maintained all requests considered by the opposition division.
- VI. Opponent 2 (respondent) replied to the appeal.
- VII. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication pursuant to Article 15(1) RPBA, expressed its preliminary opinion on the appeal.
- VIII. With a submission dated 21 February 2023, the appellant filed a set of claims of a new auxiliary request 4 and renumbered previous auxiliary requests 4 to 12 as auxiliary requests 5 to 13.
- IX. Oral proceedings took place as scheduled. At the end of the oral proceedings, the Chair announced the board's decision.
- X. The claims according to the main request are the claims as granted (see section I).

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Claim 1 of each of auxiliary requests 1, 3, 4, 5 and 13 is identical to claim 1 of the patent as granted.

Claim 1 of each of auxiliary requests 2 and 6 differs from claim 1 of the patent as granted in that it comprises the further feature "for use in a method for the prophylaxis or treatment of diseases caused by L. intracellularis, M. hyopneumoniae and Porcine circovirus".

Claim 1 of each of auxiliary requests 7, 8, 10 and 11 differs from claim 1 of the patent as granted in that it comprises the further feature "and wherein the immunological active component of Porcine circovirus comprises a live modified form, a killed form, or an immunological active part of Porcine circovirus".

Claim 1 of each of auxiliary requests 9 and 12 differs from claim 1 of the patent as granted in that it comprises the further features "and wherein the immunological active component of Porcine circovirus comprises a live modified form, a killed form, or an immunological active part of Porcine circovirus; for use in a method for the prophylaxis or treatment of diseases caused by L. intracellularis, M. hyopneumoniae and Porcine circovirus".

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

D2 WO 96/39629 A1

D19 WO 97/20050 A1

D20 WO 02/26250 A2

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- D39 F. Haesebrouck et al., Vet. Microbial. 100, 2004, 255-268
- D40 C. J. H. Dale et al., "Vaccination against proliferative enteropathy in pigs", in P. D. Cranwell (Ed.), "Manipulating Pig Production VI" Australian Pig Science Association, Werribee, Victoria, Australia, 1997, 182
- D43 Extended European search report for European patent application No. 06 738 652.4
- XII. The appellant's arguments, where relevant to the decision, are summarised as follows.

Main request (patent as granted)

Amendments (Article 100(c) EPC) - claim 1

The earlier application disclosed combination vaccines comprising an Lawsonia intracellularis (L. intracellularis) antigen and antigens from one or more other swine pathogens (see for example page 1, lines 10 to 15 and page 22, lines 2 to 7). The technical contribution of the patent was that L. intracellularis antigens could be used in combination with one or more immunological active components of one or more other swine pathogens without causing interference (paragraphs [0066], [0073], [0079] and [0084] of the patent, with identical passages in the earlier application).

The combination vaccine was further defined in the paragraph bridging pages 27 and 28 of the earlier application, the pathogens being referred to by numbers which were defined on page 26, line 15 to page 27,

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line 16 and included M. hyopneumoniae (14a) and PCV (17).

A preferred combination vaccine, identified in the earlier application as [combo 1], comprised an L. intracellularis antigen and one or more modified live microorganisms, one or more killed microorganisms or one or more immunological active part(s) of one or more of 44 different pathogenic microorganisms (see page 27, lines 8 to 16 to page 28, line 16 of the earlier application).

Among the embodiments of [combo 1] disclosed in the earlier application were [combo 147] and [combo 148] for which the immunological active component was effective for the treatment and/or prophylaxis of infections caused by the swine pathogens Mycoplasma hyopneumoniae (M. hyopneumoniae) and Porcine circovirus (PCV) (see paragraph bridging pages 46 and 47). [Combo 148] further defined the immunological active component as a live modified form, a killed form or an immunological active part of the swine pathogens M. hyopneumoniae and PCV.

The claimed combination vaccine had a basis in the earlier application according to four different lines of argument.

According to the "divisional argument", the earlier application individually disclosed several combination vaccines ("combos") which were all separate embodiments for each of which a divisional application could be filed, as evident from document D43 for example. The number of pathogens and "combos" individually disclosed in the earlier application was irrelevant, and the decision to base the claims on [combo 147] and

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[combo 148] did not amount to a selection from a first list of 775 "combos".

To arrive at the claimed combination vaccine from the disclosure of [combo 147] and [combo 148] in the paragraph bridging pages 46 and 47 of the earlier application, a single selection of killed L. intracellularis antigen was necessary from the essentially three alternative L. intracellularis antigens disclosed on page 24, lines 5 to 10 of the earlier application. Such killed L. intracellularis vaccines were disclosed, for example, in documents D2, D19 and D20 referred to in the earlier application (see page 26, lines 7 to 10) and in document D40. It was irrelevant for this single selection whether or not the earlier application contained a pointer to a different L. intracellularis antigen in the examples and claim 5.

No impermissible second selection of the stated killed M. hyopneumoniae antigen was necessary to arrive at the claimed combination vaccine, because the earlier application contained a pointer to killed M. hyopneumoniae by only disclosing commercial killed M. hyopneumoniae vaccine products for use in the combination vaccine (see the eight commercial M. hyopneumoniae vaccines disclosed on pages 151 to 153). No other M. hyopneumoniae vaccines were disclosed in the earlier application. A killed M. hyopneumoniae was therefore the particularly preferred option within the list of the three options disclosed in the paragraph bridging pages 46 and 47.

A further pointer to killed *M. hyopneumoniae* was present in the skilled person's common general knowledge that killed *M. hyopneumoniae* was effectively used as a vaccine against *M. hyopneumoniae* infections

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(see the second paragraph of the left-hand column on page 263 of the review article D39). It was irrelevant that the vaccine described in document D39 contained an adjuvant; the skilled person would in any case understand from document D39 that killed

- M. hyopneumoniae was the preferred vaccine against
- M. hyopneumoniae infection. In fact, since no other
- M. hyopneumoniae vaccines were available, using killed
- M. hyopneumoniae was the only option for the skilled person wanting to put [combo 148] of the earlier application into practice.

In a second line of argument, the "T 12/81 argument", killed M. hyopneumoniae had been selected from a threemember list, which was not a list "of some length" as defined in point 13 of the Reasons of decision T 12/81. This was clear from the established case law of the boards of appeal, which has it that a list of only two options (see T 305/13, point 5 of the Reasons) was not a list of "sizeable length" (see T 615/95, point 6 of the Reasons), in particular in view of the "disclosure status" of the individualised embodiment (see T 783/09, points 5.2 to 5.6 of the Reasons). Each of the three options in this list was spelled out and reflected what the skilled person would consider to be possible alternatives for vaccines against swine pathogens. No new technical information could arise from selecting a member of this list. This reasoning was also in line with decision T 12/81, points 7 and 8 of the Reasons, in which it was found that all the combinations of twenty starting compounds with five different methods were disclosed.

According to a third line of argument, the "pure list argument", to arrive at the claimed subject-matter only two selections from lists of only three members had to

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be made in each case, when taking into account the first selection of the *L. intracellularis* antigen. This was not impermissible because neither of the two lists was of some length and no surprising subject-matter arose from any of the only nine possible options.

Lastly, according to the "all permutations are disclosed argument", in the exceptional situation of the earlier application, which demonstrated for the first time that L. intracellularis antigens did not cause immune interference when combined with antigens from other pathogens, each permutation of the two lists had to be considered disclosed. The earlier application disclosed that L. intracellularis could be combined with any other antigen, disclosing explicitly a combination of antigens from the three pathogens recited in the claim. Any form of each of the antigens could be used in the combination vaccine. There was no need to spell out more details in the earlier application. Hence, the skilled person, using common general knowledge, was not presented with any new technical information by the claimed subject-matter, in line with decision G 2/10 (see Headnote 1b) and page 36).

Auxiliary requests 1 to 13
Amendments (Article 76(1) EPC) - claim 1

The appellant did not submit any specific arguments in relation to these auxiliary requests.

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XIII. The respondent's arguments relevant to the decision are summarised as follows.

Main request (patent as granted)

Amendments (Article 100(c) EPC) - claim 1

Multiple independent and arbitrary selections from different lists of equal alternatives were required in order to arrive at the claimed combination vaccine, which thus singled out a new and arbitrary combination of features not disclosed in the earlier application as filed.

The first arbitrary selection concerned [combo 147] and [combo 148], i.e. a combination of antigens of the three pathogens recited in the claim, from a large number of equivalent alternatives disclosed on pages 28 to 173 of the earlier application. The second selection concerned the form of the M. hyopneumoniae antigen from three equivalent alternatives disclosed in the context of [combo 148] in the paragraph bridging pages 46 and 47 of the earlier application. The third selection was the L. intracellularis antigen from at least four alternatives disclosed on page 24, lines 5 to 10 of the earlier application. A further impermissible selection was the PCV antigen from [combo 147], which was not allowable since the M. hyopneumoniae antigen was selected within [combo 148], which also defined the antigen for PCV.

The earlier application did not contain any pointer to the killed *M. hyopneumoniae* antigen. *M. hyopneumoniae* antigens were not used in any of the examples. The list of commercial vaccines disclosed on pages 151 to 153 of the earlier application belonged to a different vaccine combination identified as [combo 775], which could not

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point to an embodiment within [combo 147] and [combo 148]. In any case, listing eight commercial vaccines containing killed *M. hyopneumoniae* in a large list of 120 alternative commercial vaccines was not a pointer to killed *M. hyopneumoniae*. Document D39 did not disclose that a killed *M. hyopneumoniae* bacterium was the only solution for an *M. hyopneumoniae* vaccine; it merely disclosed that adjuvanted whole-cell *M. hyopneumoniae* preparations induced partial protection. This teaching was not a pointer to using killed *M. hyopneumoniae* in a vaccine combination of the earlier application.

The combination of the antigens as defined in the claim was comparable with the situation described in point 13 of decision T 12/81 since it concerned the combination of two products. Points 7 and 8 of that decision were irrelevant for the case in hand since they concerned the combination of a product with a method.

Decision T 305/13 was irrelevant too because it dealt with a feature for which only two alternatives existed (therapeutic versus non-therapeutic).

The examples of the earlier application related to a single combination vaccine comprising three specific commercially available vaccines. Results concerning a lack of interference between the antigens present in this particular vaccine combination were specific to these antigens; they neither applied to any other vaccine combination nor made it possible to draw any conclusions on those combinations. This was also evident from the disclosure in the paragraph bridging pages 168 and 169 and lines 13 to 16 of page 173 of the earlier application. It was therefore not true that there was an exceptional situation in which all the

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permutations from the two lists thus had to be considered disclosed in the earlier application.

Auxiliary requests 1 to 13
Amendments (Article 76(1) EPC) - claim 1

Claim 1 of each of these auxiliary requests contained subject-matter that extended beyond the content of the earlier application as filed for the same reasons as claim 1 of the patent as granted.

XIV. The parties' requests were as follows.

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution; alternatively, that the patent be maintained as granted; further alternatively that the patent be maintained in amended form based on the set of claims of one of auxiliary requests 1 to 3 filed on 25 February 2021, or auxiliary request 4 filed on 21 February 2023, or auxiliary requests 5 to 13, filed on 25 February 2021 as auxiliary requests 4 to 12. The appellant further requested that document D43 be admitted into the proceedings.

The respondent requested that the appeal be dismissed or, alternatively, that the case be remitted to the opposition division for further prosecution.

The respondent also requested that all auxiliary requests 1 to 13 and document D43 not be admitted into the proceedings.

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Reasons for the Decision

Admittance and consideration of auxiliary requests 1 to 3 and 5 to 13 (Article 12(2) RPBA), auxiliary request 4 and document D43 (Article 13(2) RPBA)

- 1. The respondent requested that auxiliary requests 1 to 13 and document D43 not be admitted into the appeal proceedings. Auxiliary requests 1 to 3 and 5 to 13 are identical to auxiliary requests 1 to 12 considered in the decision under appeal. Pursuant to Article 12(2) RPBA, a party's appeal case has to be directed inter alia to the requests on which the decision under appeal was based, and the EPC does not provide a legal basis for excluding, in appeal proceedings, requests or evidence which were already admitted into the opposition proceedings, all the more so when the impugned decision was based on them (see e.g. decisions T 1852/11, point 1.3 of the Reasons, and T 1525/17, point 4.3 of the Reasons; Case Law of the Boards of Appeal, 10th edition 2022, hereinafter "Case Law", V.A.3.4.4). Since the very aim of appeal proceedings is to review the decision under appeal, any such submissions are automatically part of the appeal proceedings. The board therefore does not have any discretion not to consider auxiliary requests 1 to 3 and 5 to 13 on appeal.
- 2. The board also decided to admit and consider auxiliary request 4 and document D43 in the proceedings, pursuant to Article 13(2) RPBA, but in view of the outcome of the case in hand, it is not necessary to provide reasons for this part of the decision.

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Main request (patent as granted)
Amendments (Article 100(c) EPC)

- 3. Whether or not a claim contains subject-matter that extends beyond the application or the earlier application as filed is to be evaluated according to the "gold standard" as set out in decision G 2/10 of the Enlarged Board of Appeal (OJ EPO 2012, 376, point 4.3 of the Reasons). According to this standard, it must be assessed what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed.
- 4. It is established case law of the boards of appeal that features pertaining to separate embodiments of the application cannot be combined in order to artificially create a particular embodiment (see decisions cited in Case Law, II.E.1.6.1). Accordingly, a combination of features singled out by selection from two separate independent enumerations is not considered to be disclosed in an application unless there is a clear pointer to that combination.
- 5. In the case in hand, the earlier application discloses combination vaccines comprising a Lawsonia intracellularis (L. intracellularis) antigen and at least one further antigen of one or more swine pathogens other than L. intracellularis (see lines 10 to 12 on page 1 and lines 2 to 7 on page 22 of the earlier application). A preferred combination vaccine defined as [combo 1] comprises an L. intracellularis antigen and one or more immunological active components effective for the treatment and or prophylaxis of infections caused by one or more of a list of more than

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70 different pathogens (or pathogen species), including Mycoplasma hyopneumoniae (M. hyopneumoniae) and Porcine circovirus (PCV) (see page 27, line 21 to page 28, line 8, and page 26, line 11 to page 27, line 16, which defines pathogen numbers (14), (14a) and (17) as Mycoplasma spp, M. hyopneumoniae and PCV, respectively), and where the immunological active component of said vaccine comprises or consists of "one or more modified live microorganisms, one or more killed microorganisms, or one or more immunological active part(s) of one or more microorganisms" selected from these pathogens (see page 28, lines 8 to 16 of the earlier application).

- 6. The earlier application then discloses 774 different embodiments of [combo 1], including, in the paragraph bridging pages 46 and 47, an embodiment where "the immunological active component of [combo 1] is effective for the treatment and/or prophylaxis of infections caused by the swine pathogens (14), in particular (14a); and (17) [combo 147], preferably said immunological active component comprises a live modified form, a killed form, or an immunological active part of said swine pathogens (14), in particular (14a); and (17) [combo 148]". [Combo 147] and [combo 148] described in this paragraph are the earlier application's only combination vaccines which contain antigens of the three pathogens recited in the claim. The recited passage on pages 46 and 47 is therefore the only possible basis in the earlier application for the claimed combination vaccine.
- 7. This passage discloses, in combination with the definition of the swine pathogens (14), (14a) and (17) and the definition of [combo 1] on pages 26 to 28, a combination vaccine comprising an *L. intracellularis*

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antigen, and an immunological active component of *M. hyopneumoniae* and PCV selected from a live modified form, a killed form or an immunological active part of said swine pathogens. "Killed *M. hyopneumoniae*" as the immunological active component of *M. hyopneumoniae* is therefore disclosed as one of three equally preferred alternatives.

- 8. "Killed L. intracellularis" is disclosed in the earlier application on page 24, lines 5 to 10. According to this passage, the preferred L. intracellularis antigen is "a complete L. intracellularis bacterium, in particular in an inactivated form (a so called killed bacterium), a modified live or attenuated L. intracellularis bacterium (a so called MLB), a chimeric vector that comprises at least an immunogenic amino acid sequence of L. intracellularis, or any other polypeptide or component, that comprises at least an immunogenic amino acid sequence of L. intracellularis".
- 9. Thus, "killed L. intracellularis" as the L. intracellularis antigen is disclosed as one of at least three equally preferred alternatives (killed bacterium, modified live bacterium, immunogenic bacterial polypeptide). It is irrelevant for this decision whether three alternatives are disclosed, as argued by the appellant, or at least four alternatives are disclosed, as argued by the respondent. In the following, the board will thus refer to at least three alternatives (see also point 25. below).
- 10. The features "killed *L. intracellularis*" and "killed *M. hyopneumoniae*" are hence both disclosed in the earlier application only in the context of two separate enumerations of several equal alternatives. The combination of these two features is consequently not

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considered disclosed unless the earlier application contains a clear pointer to this particular combination of killed antigens (see point 4. above). However, the earlier application does not contain any such pointer. The examples only concern a single vaccine combination which contains avirulent live L. intracellularis, live Erysipelothrix rhusiopathiae and avirulent live Salmonella cholerasuis, i.e. a non-killed antigen of L. intracellularis and no M. hyopneumoniae antigen at all (see the examples on pages 164 to 173). Furthermore, the earlier application does not disclose either a combination of killed bacteria in general or killed L. intracellularis or killed M. hyopneumoniae as particularly preferred antigens.

- 11. Consequently, absent any pointer to this specific combination, a combination vaccine comprising killed L. intracellularis and killed M. hyopneumoniae is singled out by two arbitrary selections from two different enumerations. The combination of features recited in the claim is therefore an artificial embodiment which is not directly and unambiguously derivable from the earlier application as filed.
- 12. The appellant submitted that the earlier application disclosed the claimed combination vaccine according to four lines of argument.

The "divisional" argument

13. The appellant argued that [combo 148] had not been selected from a first list of 775 "combos" because a divisional application could be filed for this separate embodiment. The earlier application contained a pointer to killed M. hyopneumoniae in the eight commercial M. hyopneumoniae vaccines containing killed

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M. hyopneumoniae as the antigen disclosed on page 151 (last line), page 152 (lines 4 to 5) and page 153 (line 4) of the earlier application. Reference was also made to document D39 in support of the skilled person's common general knowledge on available M. hyopneumoniae vaccines. Hence, only the feature "killed L. intracellularis" had to be selected from a single list of alternative L. intracellularis antigens, but there was also a pointer to "killed L. intracellularis" because killed L. intracellularis vaccines were disclosed in documents D2, D19 and D20 referred to in the earlier application (see page 26, lines 7 to 10) and in document D40. Moreover, the selection from a single list was allowable.

14. The board does not deny that a divisional application could be filed for [combo 148] - a combination vaccine comprising antigens of the three pathogens recited in the claim (see point 6. above). The board also acknowledges that the list of immunological active components of M. hyopneumoniae is disclosed as part of [combo 148] (see the sentence bridging pages 46 and 47 of the earlier application). Furthermore, the board agrees with the appellant that in order to arrive at a combination vaccine comprising the L. intracellularis and M. hyopneumoniae antigens recited in the claim starting from [combo 148], "killed" L. intracellularis and "killed" M. hyopneumoniae must be selected, and it has not been denied that a pointer could be present anywhere in an application, including examples and specific embodiments. The board therefore agrees with the case law cited by the appellant in support of this argument (T 686/99, T 2118/08, T 2363/10, T 1261/16) and sees no need to address these decisions in detail.

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- 15. Moreover, neither the respondent nor the board denied that vaccines comprising killed *L. intracellularis* were (commercially) available. However, this has no implications for the list of at least three equally preferred alternatives for an *L. intracellularis* antigen disclosed in the application.
- 16. The board is not persuaded that the disclosure of the eight commercial M. hyopneumoniae vaccines on pages 151 to 153 of the earlier application constitutes a pointer to killed M. hyopneumoniae. These eight M. hyopneumoniae vaccines are dispersed within a list of about 120 different commercial vaccines against various swine pathogens. This list of commercial vaccines is part of an embodiment identified as "[combo 775]" (see line 18 and 19 of page 151), which is a combination vaccine where the L. intracellularis antigen is combined "with the antigen(s), or with the final vaccine formulation" of any of the about 120 commercial vaccines listed. Hence, this [combo 775] is an alternative embodiment of [combo 1] independent of and unrelated to [combo 147] and [combo 148] on which the claimed subject-matter is based (see point 6. above). It therefore cannot be a pointer to an embodiment within [combo 147] and [combo 148].
- 17. Document D39 discloses that "[v]accination [of pigs] with commercial bacterins has become an important tool to control M. hyopneumoniae infections" and that "[t]hese vaccines, consisting of adjuvanted whole-cell preparations have been shown to induce partial protection against development of gross lesions" (second paragraph of the left-hand column on page 263). The information presented in document D39 is therefore that commercial vaccines comprising adjuvanted killed M. hyopneumoniae are used in practice and that they

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confer partial protection on *M. hyopneumoniae*—induced lesions. This disclosure neither is tantamount to killed *M. hyopneumoniae* being the only possible *M. hyopneumoniae* vaccine nor prompts the skilled person to prefer killed *M. hyopneumoniae* as the antigen in [combo 148] over the other two options recited in the earlier application.

- 18. Furthermore, it does not follow from the above-cited passage of document D39 and the fact that the earlier application only mentions commercially available M. hyopneumoniae containing killed M. hyopneumoniae that the skilled person would have considered that only killed M. hyopneumoniae was meant out of the three options disclosed in the earlier application for M. hyopneumoniae antigens in the context of [combo 148] (see the sentence bridging pages 46 and 47), because the skilled person is not restricted to using commercially available vaccines. It was neither common general knowledge nor was any evidence submitted that demonstrated that the other options disclosed in the earlier application as equally preferred alternatives, i.e. a live modified form or an immunological active component of M. hyopneumoniae, could not actually be used as an M. hyopneumoniae vaccine.
- 19. The board is therefore not persuaded that there were pointers for selecting killed *L. intracellularis* and killed *M. hyopneumoniae*. The appellant's first line of argument is therefore not persuasive.

The "T 12/81" argument

20. According to the appellant's second line of argument, a three-member list was not a list "of some length" as defined in decision T 12/81. Since in decision T 305/13

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the entrusted board held that a list of two options was not of some length, a list of three options could not be of some length either.

- 21. However, the board notes that in the case on which decision T 305/13 is based, the selection concerned the two options "therapeutic" and "non-therapeutic", i.e. a situation where only two alternatives were actually possible (point 5 of the Reasons). No conclusions on the list of three options presented in the case in hand can be drawn from this particular situation.
- 22. Moreover, the relevant question for assessing added subject-matter is not the precise size of a list but whether or not a combination of features selected from different lists presents new technical information. The answer to this question is determined by the content of both lists and by how these lists are presented in the application. This is also evident from decisions T 12/81 and T 783/09 cited by the appellant in support of its arguments. In T 12/81, the deciding board distinguished between the selection from a list of reaction methods (points 7, 8 and 13 of the Reasons) and two independent lists of two products (second sentence of point 13 of the Reasons), for which different disclosure criteria applied.
- 23. In T 783/09, a combination of one of two alternative DPP-IV inhibitors and one of 22 further "antidiabetic compound[s]" identified in the same paragraph as a "very preferred embodiment" was found to individually disclose the "very preferred" combinations of each of the two inhibitors with each of the 22 further antidiabetic compounds (see points 5.2 to 5.6 of the Reasons). In the case in hand, neither of the lists consists of only two compounds, nor were the

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combinations presented in the same paragraph of the earlier application as a "very preferred embodiment". The "disclosure status" in the case on which decision T 783/09 is based was therefore different from that in the case in hand and T 783/09 is irrelevant. The appellant's second line of argument therefore also fails to persuade the board.

The "pure list" argument

- In a third line of argument, the appellant considered that no new subject-matter arose even when both lists and thus both separate selections were taken into account, since each of the lists consisted of only three options and there were only nine possible combinations. In the board's view, however, the decisive issue is not the actual number of possible options but whether singling out a combination of two options creates a new embodiment (see points 4. and 20. to 23. above).
- 25. In the case in hand, a combination of killed L. intracellularis and killed M. hyopneumoniae is singled out in the claim. The application, however, teaches that both the L. intracellularis antigen and the M. hyopneumoniae antigen could be present in the combination vaccine in any of the forms presented, irrespective of the other antigen. The teaching that the antigen for both in the specific combination described in the earlier application as [combo 148] should be the respective killed form is thus not derivable from the earlier application as filed. It is irrelevant for this assessment whether the L. intracellularis antigen list has three, four or more entries.

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The "all permutations are disclosed" argument

- In a fourth line of argument, the appellant asserted that the earlier application demonstrated for the first time that *L. intracellularis* antigens did not cause immune interference when combined with antigens from other pathogens, and that it explicitly disclosed combination vaccines containing antigens of the three pathogens recited in the claim, which could be used in any form. Each permutation of the two lists had to be considered disclosed because, against the background of the general teaching of the application, they did not present the skilled person with any new technical information.
- 27. In support of its arguments, the appellant referred to page 166, lines 2 to 6, the paragraph bridging pages 168 and 169, page 171, lines 7 to 9 and page 173, lines 13 to 16 in the examples of the earlier application. These passages concern a specific vaccine combination containing commercially available avirulent live L. intracellularis, live Erysipelothrix rhusiopathiae and avirulent live Salmonella cholerasuis and demonstrate that, in this specific combination, these three commercial vaccines do not interfere with each other.
- The board fails to see how this teaching of a lack of interference in a combination of three commercially available vaccines consisting of live

 L. intracellularis, live Erysipelothrix rhusiopathiae and live Salmonella cholerasuis could have an impact on the selection of killed L. intracellularis and killed

 M. hyopneumoniae from the lists disclosed on pages 24, 26 and 27. Contrary to the appellant's arguments, the examples neither demonstrate that any

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- L. intracellularis antigen in any form could be combined with the antigens of any other pathogen without causing interference, nor allow any conclusions to be drawn on killed L. intracellularis and M. hyopneumoniae antigens. The appellant's fourth line of argument is therefore not persuasive either.
- 29. Since the board concluded that the earlier application does not provide a basis for a combination vaccine comprising killed *L. intracellularis* and killed *M. hyopneumoniae*, there is no need to form an opinion on the respondent's objection raised in respect of the definition of the PCV antigen in the claim.
- 30. In view of the above considerations, claim 1 of the patent as granted contains subject-matter that extends beyond the content of the earlier application as filed. Therefore, Article 100(c) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1 to 13 - claim 1 Amendments (Article 76(1) EPC)

- 31. Claim 1 of each of auxiliary requests 1 to 13 relates to a combination vaccine comprising killed *L. intracellularis*, killed *M. hyopneumoniae* and an immunological active component of PCV (see section IV.).
- 32. Claim 1 of each of auxiliary requests 1 to 13 therefore contains subject-matter that extends beyond the content of the earlier application as filed for the same reasons as claim 1 of the main request (see points 3. to 30. above). Therefore, none of these auxiliary requests meets the requirements of Article 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



B. Brückner

T. Sommerfeld

Decision electronically authenticated