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Case Number: T 0148/15 - 3.3.04

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Language of the proceedings: EN

Title of invention:
Multivalent canine vaccines against Leptospira bratislava and other pathogens

Patent Proprietor:
Zoetis Services LLC

Opponents:
Intervet International B.V.
Merial Limited

Headword:
Canine vaccine against leptospira bratislava/ZOETIS

Relevant legal provisions:
EPC Art. 54, 84, 111(1), 114(2), 123(2)
RPBA Art. 13(1)

Keyword:
Main request (after amendment) - novelty (yes); remittal of the case to the opposition division (yes)

Decisions cited:
G 0001/04, T 0578/06, T 1859/08

Catchword:

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0148/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 10 January 2019

Appellant: (Patent Proprietor)	Zoetis Services LLC 10 Sylvan Way Parsippany, NJ 07054 (US)
Representative:	Mannion, Sally Kim Zoetis UK Limited Walton Oaks Dorking Road Tadworth Surrey KT20 7NS (GB)
Respondent I: (Opponent 01)	Intervet International B.V. P.O. Box 31 Wim De Körverstraat 35 5830 AA Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Respondent II: (Opponent 02)	Merial Limited 3239 Satellite Blvd Duluth, GA 30096-4640 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 1 December 2014 revoking European patent No. 1799253 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	M. Blasi
Members:	R. Morawetz
	A. Chakravarty

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 1 799 253. The patent, entitled "*Multivalent canine vaccines against Leptospira bratislava and other pathogens*", derives from European patent application No. 05789769.6 which was filed as international application under the PCT published as WO 2006/038115 (application as filed or application).

II. Claims 1, 2 and 3 as granted read as follows:

"1. A vaccine composition for use in immunizing dogs against infection caused by *Leptospira bratislava* comprising a *Leptospira* cell preparation of *Leptospira bratislava* and a carrier.

2. The vaccine composition of claim 1, wherein said *Leptospira* cell preparation further comprises a cell preparation of at least one of *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae*, or *Leptospira pomona*, wherein the amount of each *Leptospira* strain in the vaccine composition is in the range of about 100-3500 nephelometric units per vaccine dose.

3. A combination vaccine for use in immunizing dogs against canine pathogens comprising the composition of claim 2, and further comprises an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus, an attenuated strain of canine parvovirus (CPV), and a carrier,

wherein the amount of each attenuated strain of virus in said vaccine is in the range of 10^2 to 10^9 $TCID_{50}$ per dose."

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

D9 US 5843456 (1998)

D10 Tronel J.P. et al., Canine Infectious Diseases: From Clinics to Molecular Pathogenesis, Carmichael L. (Ed.) (1999), page 1

D12 Foster & Smith, Inc., News (2000), Fort Dodge releases new leptospirosis vaccine, page 1

D14 Schultz R.D., Recent Advances in Canine Infectious diseases, Carmichael L.E. (Ed.) (2000), pages 1 to 9

D15 Gueguen S. et al., Anclivepa Congress, Rio Brazil (2000), Poster

D16 Davol P.A (2001), Canine Leptospirosis, http://www.labbies.com/lepto.htm

D18 WO 02/02139 (10 January 2002)

D19 WO 03/024354 (27 March 2003)

D20 Klaasen H.L.B.M. et al., Veterinary Microbiology (2003), vol. 95, pages 121 to 132

D24 Duramune MAX 5-CVK 4L (2012), http://www.bullwrinkle.com/ShoppingPages/

D25 WO 2004/067031 (12 August 2004)

D35 WO 99/59630 (25 November 1999)

D39 Ellis W.A. et al., The Veterinary Record (1989), vol. 125, pages 319 to 321

D42 Intervet (2002), Product Guide, Nobivac Lepto, Nobivac DHPPi, pages 161, 164, 167

D47 André-Fontaine G. et al., The Veterinary Record (2003), vol. 153, pages 165 to 169

D56 Faine S., Leptospira and leptospirosis (1994), pages 174 to 184

D61 Naiman, B.M. et al., Infection and Immunity (2001), vol. 69, pages 7550 to 7558

IV. Two oppositions were filed against the patent, which 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 100(c) EPC. The opposition division decided that the subject-matter of claims 1 and 3 of the main request did not meet the requirements of Article 123(2) EPC. Moreover, the subject-matter of claim 3 of each of auxiliary requests 1 to 4 was found not to meet the requirements of Article 123(2) EPC. The subject-matter of claims 1 and 3 of auxiliary request 5, and of claim 1 of auxiliary requests 6 and 9 *inter alia* was considered to be anticipated by the disclosure of document D25. The subject-matter of claim 1 of auxiliary requests 7, 8, 10 and 11 *inter alia* was held not to meet the requirements of Article 123(2) EPC.

V. With the statement of grounds of appeal, the appellant filed sets of claims of a main request and auxiliary requests 1 to 4, 4a, 5, 5a, 6 to 11, with the main request and auxiliary requests 1 to 4, 5a, 6 to 11 corresponding to the main request and auxiliary requests 1 to 11, considered by the opposition division. Auxiliary requests 4a and 5 were newly filed requests.

VI. Opponents 01 and 02 are respondents I and II in these appeal proceedings.

VII. The board appointed oral proceedings as requested by the parties, and issued a communication pursuant to Article 15(1) RPBA, in which it indicated, *inter alia*, that it intended to remit the case to the opposition division for further prosecution should it find the appeal allowable.

VIII. In response, the appellant filed claims of auxiliary requests 12 and 13.

IX. At the oral proceedings before the board, the appellant filed an amended auxiliary claim request 6 thereby replacing auxiliary request 6. The pending main and auxiliary claim requests 1 to 4, 4a, 5, 5a were withdrawn. The amended auxiliary request 6 became the main request and the lower ranking auxiliary requests, i.e. auxiliary requests 7 to 13, were renumbered and became auxiliary requests 1 to 7.

Claims 1 to 3 of the main request read as follows:

"1. A vaccine composition for use in protecting dogs against infection caused by *Leptospira bratislava*

comprising a *Leptospira* cell preparation of *Leptospira bratislava* and a carrier.

2. The vaccine composition of claim 1 for the use of claim 1, wherein said *Leptospira* cell preparation further comprises a cell preparation of at least one of *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae*, or *Leptospira pomona*, wherein the amount of each *Leptospira* strain in the vaccine composition is in the range of about 100-3500 nephelometric units per vaccine dose.

3. A combination vaccine for use in protecting dogs against infection caused by *Leptospira bratislava* comprising the composition of claim 2, wherein the composition comprises a cell preparation of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae*, and *Leptospira pomona*, and further comprises an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus, an attenuated strain of canine parvovirus (CPV), and a carrier, wherein the amount of each attenuated strain of virus in said vaccine is in the range of 10^2 to 10^9 $TCID_{50}$ per dose."

Dependent claims 4 to 13 of the main request further define the vaccine composition and the combination vaccine of claims 1, 2 and 3.

X. At the end of the oral proceedings the Chair announced the board's decision.

XI. The appellant's arguments, submitted in writing and during the oral proceedings, are summarised as follows:

Main request

Amendments (Article 123(2) EPC) - claims 1 and 3

The subject-matter of claim 1 found a basis in claims 1 and 9 as filed in combination with page 1, lines 16 to 18 of the description as filed, which disclosed the feature "*protecting dogs against infection caused by Leptospira bratislava*".

A combination vaccine comprising attenuated strains of CD, CAV-2, CPI and CPV and a preparation of five *Leptospira* serovars was disclosed in claims 13 and 14 as filed in combination with claims 16 and 19 to 22 as filed. The application thus disclosed the subject-matter of claim 3 on page 1, lines 16 to 18 of the description as filed in combination with claims 13, 14, 16 and 19 to 22 as filed.

Clarity (Article 84 EPC) - claims 1 and 3

The meaning of the term "protecting" used in the claims was clear in the context of the claims, it meant protecting against infection.

Amendments (Article 123(3) EPC) - claims 1 and 3

Claim 1 was a second medical use claim and the vaccine comprising *L. bratislava* was the active agent mediating the protective immunising effect. The term "protecting" was not broader than the term "immunizing", particularly not in the context of a vaccine. Replacing "immunizing" with the term "protecting" in the context

of a claim to a vaccine did not extend the scope of protection.

It was entirely irrelevant that protection against malaria could be achieved by a mosquito net, since this protection would not be mediated by a vaccine containing the active agent. The mosquito net was not a vaccine and no analogy with the present invention could be derived.

Claim 3 was limited compared to claim 3 as granted, as it required all five *Leptospira* strains to be present.

Novelty (Article 54 EPC) - claims 1 to 13

Document D25

Protecting dogs against infection with *L. bratislava* was a technical feature of claim 1. For document D25 to anticipate the claimed subject-matter, it had to be "beyond doubt - not merely probable" that document D25 disclosed an effective vaccine or at least that it could be concluded with the required certainty that the protective effect would be present, see also decisions T 158/96, T 385/07 and T 1859/08.

However, the effect of protecting dogs against *L. bratislava* was not directly and unambiguously derivable from document D25. Document D25 did not contain any data or evidence that a protective immune response against *L. bratislava* was induced in dogs. In particular, the passages of document D25 relied on by the respondents did not provide any teaching that the vaccine comprising *L. bratislava* was effective in the context of a combination vaccine.

The only example relating to the safety and efficacy of a vaccine containing *Leptospira* antigens was Example 4, using the approved vaccine VANGUARD Plus® 5/CV-L. It demonstrated protection against challenge with CPV and CVV. Challenge with a *Leptospira* serovar was not described. This example did not verify that the vaccine could effectively protect against *Leptospira*.

It was not correct that the wording of document D25 did not allow any doubts that the vaccine compositions containing *L. bratislava* could protect against infection with *L. bratislava*.

Document D25 started from the premise that interference was a problem in dogs, see page 2, line 29 to line 38. This passage affected the skilled person's understanding of the description of document D25, raising doubts about whether or not vaccine compositions containing *L. bratislava* could protect against infection with that organism. Moreover, page 2 of document D25 did not say that the interference problem was caused by the *B. bronchiseptica* component or that it was overcome by provision of the new *B. bronchiseptica* component.

The involvement of efficacy interference seemed to be a general problem in developing combination vaccines, and seemed to be dependent on the host, since combination vaccines for cats were known, see document D25, page 2, lines 35 to 38.

Document D42, a product leaflet, did not constitute proof that interference was not a problem in dogs. Considerable research effort went into developing that combination vaccine.

In summary, the disclosure of document D25 did not put the skilled person in possession of the present invention. This view was not affected by prior art describing vaccination of dogs using *Leptospira* vaccines not containing *L. bratislava* (see e.g. documents D9, D10, D12, D14, D15, D16, D19, D20, D24 or D42) or by document D39 which disclosed a cell preparation of *L. bratislava* to induce an immune response against *L. bratislava* in pigs, not in dogs.

It was not correct that, since the therapeutic application of *L. bratislava* was known already from document D39, decisions T 158/96, T 385/07 and T 1859/08 were not applicable in the present case. Document D39 related to pigs and did not show a protective effect against infection with *L. bratislava* in dogs.

Document D18

Claim 2 of document D18 did not define the animal to be protected. To arrive at the choice of dogs as the animal, a selection from a list in claim 2 had to be made. To arrive at the *L. bratislava* antigen, a selection from a second list in claim 3 was necessary. Finally, pages 8 and 9 did not disclose *L. bratislava* in connection with dog, but only in connection with pig.

Document D35

Document D35 did not disclose a *Leptospira* cell preparation as required by claim 1. Rather, the antigens disclosed on page 16, lines 8 to 21, were in the form of whole heterologous proteins, or portions thereof (see page 16, lines 22 to 23) and the

protection in dogs was for kennel cough, and not for an infection caused by *L. bratislava* (see page 32, lines 28 to 31).

XII. The arguments of the respondents, submitted in writing and during the oral proceedings, are summarised as follows:

Main request

Amendments (Article 123(2) EPC) - claims 1 and 3

The combination of features in claims 1 and 3 had not been individualised as such in the application as filed and thus added subject-matter.

There was a double recitation of *L. bratislava* in claim 3 due to the repeated use of the term "comprising". Claim 3 thus covered different forms of *L. bratislava* and found no basis on page 1 of the application as filed.

Clarity (Article 84 EPC) - claims 1 and 3

The term "protecting" meant "different things to different people". In light of the definition given in the description, the expression "protecting against infection" had to be considered as being undefined and therefore unclear.

When reading the opposed patent, in particular examples 3 and 6, the skilled person could not understand what "protecting against *Leptospira bratislava*" meant and hence had to guess what was meant by the term "*protection*" in claims 1 and 3.

Amendments (Article 123(3) EPC) - claims 1 and 3

Claims 1 and 3 encompassed subject-matter which extended the scope of protection.

The opposition division had construed "protecting" to be narrower than "immunizing". However, in certain circumstances "protecting" could be also constructed to be broader than "immunizing" because immunisation was just one way in which a subject could be protected against a disease or infection. In other words, a subject could be protected against a disease/pathogen without immunising against said disease/pathogen.

There existed diseases which could be prevented by immunisation and other measures, e.g. Typhoid, Rabies and Lyme disease. Additionally there existed diseases which could not be immunised against but might be prevented by other protective measures, e.g. Malaria.

Claims 1 and 3 therefore encompassed protecting means other than protecting a dog against infection caused by *L. bratislava* by immunising with a vaccine composition (or combination vaccine) comprising a *L. bratislava* cell preparation. This interpretation was supported by the definition of the term "protection" in paragraph [0041] of the patent.

Novelty (Article 54 EPC) - claims 1 to 13

Document D25

Document D25 disclosed a combination vaccine including attenuated CDV, CAV-2, CPI virus, CPV, CCV, and a preparation of five *Leptospira* serovars (*L. bratislava*, *L. canicola*, *L. grippotyphosa*, *L. icterohaemorrhagiae*

and *L. pomona*), see page 3, lines 33 to 38 and page 4, lines 7 to 11. Said combination vaccine was used for protecting dogs against diseases caused by canine pathogens, see page 1, lines 13 to 14. Document D25 therefore disclosed vaccine compositions comprising *L. bratislava* used for immunising dogs against *L. bratislava*.

It was not required that document D25 contained an explicit statement that a vaccine containing *L. bratislava* could induce a protective immune response against *L. bratislava* infection because disclosure could be implicit.

It was abundantly clear that the combination vaccine of document D25 was of the type which would both immunise and protect against *L. bratislava*.

The wording of document D25 did not allow any doubt that said vaccine compositions had the alleged effect. The skilled person was provided with clear instructions as to how the vaccine was to be prepared and used and which effects were to be expected, see page 12, lines 10 to 27 and page 13, lines 10 to 19.

It was almost unthinkable that the skilled reader of document D25 (especially page 9, lines 35 to 39 and claims 8, 9, 12, and 13) would have any serious doubts that a combination vaccine comprising *L. bratislava* induced a protective immune response against *L. bratislava* infection.

Document D25 disclosed the treatment of *L. bratislava* at least fifteen times throughout the document. Thus,

it clearly anticipated a therapeutic outcome of a vaccine against *L. bratislava*.

The skilled person would not have had any doubts that the combination vaccine of document D25 would induce an immune response against the antigens present in said vaccine, i.e. also against *L. bratislava*, since document D39 showed that a cell preparation of *L. bratislava* was suitable for inducing an immune response against the pathogen.

There was a very strong indication to the skilled person in document D25 that the interference problem was caused by the *B. bronchiseptica* component and not by any other component. After all, document D25 provided a new *B. bronchiseptica* component.

Decision T 578/06 made it clear that no data were required for the grant of a patent. Thus, no data were required for a document to be novelty destroying either.

Document D42 provided proof that there was no interference in dogs, see page 164.

Furthermore, there was no information on file that *L. bratislava* did not behave like the other *Leptospira* serovars/strains. The prior art described several vaccine compositions comprising cell preparations of *Leptospira* serovars other than *L. bratislava* used for vaccinating dogs against Leptospirosis (see e.g. documents D9; D10: LEPTODOG®; D12, D16 and D19: Duramune®; D14; D15; combination of Canigen® OHPPi and Canigen® L; D20: combination of Nobivac® Lepto and Nobivac® OHPPI; D24, D39, D42, D47 and D61).

The use of *L. bratislava* containing vaccines to protect against *L. bratislava* infection was known from document D39, therefore the situation differed from that in decision T 1859/08.

Document D18

Document D18 disclosed methods for protecting dogs against diseases caused by canine pathogens and multivalent vaccines which fell within the scope of the claims, see paragraph bridging pages 7 and 8, pages 8 and 9 and claims 1 to 3.

Document D35

Document D35 disclosed a genetically modified *Bordetella* expressing a heterologous antigen, for use as a live attenuated vaccine for the treatment of dogs, see page 23, 5th full paragraph. The heterologous antigen could be derived from *L. bratislava*, see page 16, 2nd paragraph and claim 42. Thus, document D35 disclosed methods for protecting dogs against disease caused by canine pathogens using combination, multivalent vaccines as claimed.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request filed as auxiliary request 6 during the oral proceedings before the board, or alternatively, on the basis of one of the sets of claims of auxiliary requests 1 to 5, filed as auxiliary requests 7 to 11 with the statement of grounds of appeal, or on the

basis of one of the sets of claims of auxiliary requests 6 or 7, filed as auxiliary requests 12 and 13 with letter dated 10 December 2018.

XIV. Both respondent I and respondent II requested that the appeal of the patent proprietor be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

Main request

Admission into the appeal proceedings

2. The set of claims of this request was filed during the oral proceedings before the board in direct response to respondent II's objection, first raised in the oral proceedings, that claims 2 and 4 to 13 of auxiliary request 6 were in fact product claims and their subject-matter thus anticipated by the disclosure of document D25.

3. The set of claims of the main request is based on the set of claims of auxiliary request 6 filed with the statement of grounds of appeal, with claims 2 and 4 to 13, amended to be in the form of purpose-limited product claims.

4. As noted above, the amendments were made in response to an objection raised for the first time during the oral proceedings and therefore could not have been filed earlier. The amendments made were straightforward and did not raise new issues, nor were they of such complexity that they required a postponement of the

oral proceedings. Finally, the respondents did not object to the admission of this request into the appeal proceedings.

5. Accordingly, the board, exercising the discretion pursuant to Article 13(1) RPBA, decided to admit this request into the appeal proceedings.

Amendments (Article 123(2) EPC) - claims 1 and 3

6. The respondents argued that subject-matter having the combination of features of claims 1 and 3 has not been disclosed in an individualised manner in the application as filed.

7. The board notes that the application as filed discloses that the "*invention relates to vaccines containing Leptospira bratislava and the use thereof for protecting dogs against infection caused by Leptospira bratislava*" (see page 1, lines 16 to 18) while claim 1 as filed discloses a "*vaccine composition comprising a Leptospira cell preparation of Leptospira bratislava and a carrier*".

8. The board considers that the skilled person understands that the vaccine composition according to claim 1 of the application constitutes a preferred embodiment of "*a vaccine containing Leptospira bratislava*" that can be used according to the invention, as disclosed on page 1, lines 16 to 18. Accordingly, the board is satisfied that a skilled person would consider the subject-matter of claim 1 directly and unambiguously disclosed on page 1, lines 16 to 18 of the application as filed, when read in combination with the disclosure of claim 1 of that application.

9. As regards the subject-matter of claim 3, the board notes that claim 13 as filed, which depends on claim 1 as filed, discloses a vaccine composition comprising a *Leptospira* cell preparation of *Leptospira bratislava (L. bratislava)* and a carrier which "*further comprises a cell preparation of Leptospira canicola, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, and Leptospira pomona*" while claim 14 as filed further defines the amount of each *Leptospira* strain in the vaccine composition of claim 13 to be "*in the range of about 100-3500 nephelometric units per vaccine dose*".

10. Furthermore, claim 16 as filed discloses a "*combination vaccine for immunizing dogs against canine pathogens comprising the composition of claim 13 and further comprising an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus, an attenuated strain of canine parvovirus (CPV), and a carrier*", while claims 19 to 22 as filed define the amounts of the various attenuated viral strains to be "*in the range of 10^2 to 10^9 $TCID_{50}$ per dose*".

11. Thus, the skilled person reading claims 13, 14, 16 and 19 to 22 of the application as filed would consider a combination vaccine comprising a cell preparation of the five *Leptospira* serovars including *L. bratislava* and further comprising attenuated strains of four canine viruses as defined in present claim 3 to be directly and unambiguously disclosed as a preferred embodiment of the invention. The board is furthermore satisfied that a skilled person would understand that this combination vaccine can be used according to the invention as disclosed on page 1, lines 16 to 18. The board concludes that page 1, lines 16 to 18, in

combination with claims 13, 14, 16 and 19 to 22 of the application as filed directly and unambiguously disclose the subject-matter of claim 3.

12. During the oral proceedings, respondent II submitted that due to the repeated use of the term "*comprising*", the combination vaccine as defined in present claim 3 covered different forms of *L. bratislava* and thus comprised added subject-matter.

13. Claim 3 is directed to a combination vaccine "*comprising the composition of claim 2, wherein the composition comprises a cell preparation of Leptospira bratislava, Leptospira canicola, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, and Leptospira pomona*" (see section IX for the complete wording of the claim). In the board's opinion, the skilled person reading the claim would understand that the expression "*wherein the composition comprises*" further defines the composition of claim 2 - which composition comprises a cell preparation of *L. bratislava* and of at least one further *Leptospira* serovar out of four possible serovars - to comprise all five *Leptospira* serovars. Accordingly, there is no double recitation of *L. bratislava* nor does the claim cover different forms of *L. bratislava.* Respondent II's objection thus fails.

14. For the reasons indicated above, the board concludes that the subject-matter of the claims of the main request complies with the requirements of Article 123(2) EPC.

Clarity (Article 84 EPC) - claims 1 and 3

15. The respondents submitted that the claims lacked clarity because the term "*protecting*" meant "*different things to different people*".

16. In the board's view, the issue to be decided is whether or not the meaning of the term "*protecting*" is clear to the skilled person in the context of the claim as a whole and from the wording of the claims alone (see also opinion G 1/04, OJ EPO 2006, 334, Reasons, point 6.2).

17. Claims 1 and 3 of the main request are for a vaccine composition and a combination vaccine, respectively, "*for use in protecting dogs against infection caused by Leptospira bratislava*" (emphasis added). The board considers that the skilled person knows that if a vaccine protects a subject against infection it does so by inducing a protective humoral and/or cellular immune response in the vaccinated subject. The respondents have not argued otherwise. In view of this the skilled person reading the claims would understand that the term "*protecting*", in the context of a vaccine, refers to protection against infection by the induction of an appropriate immune response.

18. Thus, the meaning of the term "*protecting*" is clear from the wording of the claims alone. Accordingly, there is no need for the skilled person to turn to the description. The respondents' argument, based on the definition given in paragraph [0041] of the description, fails for this reason alone.

19. The board concludes that the claims of the main request meet the clarity requirements of Article 84 EPC.

Requirements of Article 123(3) EPC - claims 1 and 3

20. The respondents submitted that claims 1 and 3 of the main request did not comply with the requirements of Article 123(3) EPC.

21. As already indicated in point 17 above, claims 1 and 3 of the main request are for a vaccine composition and a combination vaccine, respectively, "*for use in protecting dogs against infection caused by Leptospira bratislava*" while claims 1 and 3 as granted were for a vaccine composition and a combination vaccine, respectively, "*for use in immunizing dogs against infection caused by Leptospira bratislava*" (see sections I and IX above; emphasis added).

22. The argument advanced by the respondents is that in certain circumstances "*protecting*" may be construed to be broader than "*immunizing*" because immunisation is just one way in which a subject can be protected against a disease or infection. Diseases exist which could be prevented by immunisation and/or other measures. As an example, protection against malaria with a mosquito net was mentioned.

23. The board does not find the respondents' line of argument persuasive. As explained in point 17 above, the skilled person knew that a vaccine protects against infection by inducing a protective immune response. The mere fact that for Typhoid, Rabies and Lyme disease, i.e. for diseases other than the claimed disease, protection means other than immunisation are available, does not mean that the skilled person reading the term

"protecting" in the context of the claim would have considered that "protecting" was to be done by means other than by inducing an immune response.

24. Therefore, the board is not persuaded that in the context of claims 1 and 3 the term "*protecting*" can be construed to be broader than the term "*immunizing*" present in claims 1 and 3 as granted. Thus, the amended claims 1 and 3 do not extend the scope of protection conferred by the claims vis-à-vis that conferred by the claims of the granted patent and the board is satisfied that claims 1 and 3 comply with the requirements of Article 123(3) EPC.

Novelty (Article 54 EPC) - claims 1 to 13

25. Claim 1 of the main request corresponds to claim 1 of auxiliary request 6 before the opposition division. In the decision under appeal, document D25 was held to anticipate the subject-matter of claim 1 of auxiliary request 6 (see point L4 of the decision). During the written appeal proceedings, further objections as regards lack of novelty of the subject-matter of the claims of the main request were raised by respondent II based on documents D18 and D35. The various objections are addressed below in turn.

Document D25

26. Document D25 relates to combination vaccines containing a *Bordetella bronchiseptica* (*B. bronchiseptica*) p68 antigen and one or more antigens of another canine pathogen and to methods for protecting dogs against diseases caused by canine pathogens using these combination vaccines (see page 1, first paragraph).

27. Document D25 discloses that the "*combination vaccines of the present invention include a Bordetella bronchiseptica p68 antigen in combination with at least one other antigen from other canine pathogens, capable of inducing a protective immune response in dogs against disease caused by such other pathogen(s)*" (see page 3, line 19 to 23).

28. A preferred combination vaccine of document D25 "*includes attenuated strains of canine distemper (CD) virus, canine adenovirus type 2 (CAV-2), canine parainfluenza (CPI) virus and canine parvovirus (CPV); an inactivated preparation preparation of a strain of canine coronavirus (CCV); a Bordetella bronchiseptica p68 protein, and an inactivated cell preparation of five Leptospira serovars (Leptospira bratislava, Leptospira canicola, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae and Leptospira pomona)*" (emphasis added, see page 3, lines 33 to 38).

29. The board is thus satisfied that document D25 discloses multivalent combination vaccines which include a *B. bronchiseptica* p68 antigen and an inactivated cell preparation of *L. bratislava* together with antigens from various other canine pathogens and their use for protecting dogs against diseases caused by any of these canine pathogens, including *L. bratislava*.

30. Claim 1 is drafted as a second medical use claim, where novelty is derived from the intended medical use and attaining the claimed therapeutic effect is a functional technical feature of the claim. Therefore, for the purpose of assessing novelty it has to be examined whether or not the therapeutic effect - protecting dogs against infection caused by *L. bratislava* - is also directly and unambiguously

disclosed in document D25 (see also decision T 1859/08 of 5 June 2012, Reasons, point 7).

31. The board notes that it is undisputed that document D25 does not disclose any data showing that the use of such a multivalent combination vaccine in dogs protects them against infection caused by *L. bratislava*.

32. The opposition division argued that "*the wording of D25 does not allow any doubt that said vaccine compositions have the alleged effect*" (see decision under appeal, point L4). Similar arguments were advanced by the respondents during appeal.

33. While the opposition division did not cite any particular passage of document D25 in support of its conclusion, the appellants relied on selected passages on pages 9, 12 and 13 of document D25.

34. The board considers that these passages would be read and understood by the skilled person in the light of the whole content of document D25.

35. Document D25 starts from the premise that efficacy interference, i.e. "*a failure of one or more antigens in a combination composition to maintain or achieve efficacy because of the presence of the other antigens in the composition*" is a problem in dogs (see page 2, lines 29 to 38).

36. On page 3 of document D25, a combination vaccine comprising *inter alia* also *L. bratislava* is disclosed (see also point 28 above), albeit without any indication of whether or not this vaccine avoids the problem of efficacy interference for all of the antigens it comprises and, more importantly, without

any explanation as to why - contrary to what is stated on page 2 (see point 35) - interference is not a problem for this combination vaccine in dogs.

37. On page 9, lines 35 to 38, document D25 states under the heading "*p68 combination vaccines*" that "[*t*]*he combination vaccine compositions of the present invention do not exhibit efficacy interference*".

38. On page 12, lines 10 to 27 and page 13, lines 10 to 19, document D25 then discloses that a preferred combination vaccine includes the antigenic components of the p68/5CV combination vaccine or the p68/DA_2PP combination vaccine as well as inactivated whole cell preparations of five *Leptospira* species including *L. bratislava*.

39. While these passages also provide instructions as to how the vaccines are to be prepared and administered to dogs, they are silent about any effects achieved and do not allow any conclusion to be drawn with regard to the actual existence of a protective effect against infection caused by *L. bratislava*.

40. Examples 1 to 3 and 5 of document D25 disclose the use of a p68 *B. bronchiseptica* vaccine - comprising *B. bronchiseptica* but not any other antigen - while in example 4, a combination vaccine, VANGUARD® Plus 5/CV-L, which comprises neither *B. bronchiseptica* nor *L. bratislava* is used in puppies.

41. In the board's view, the skilled person reading the statement on page 9 of document 25 (see point 37), in the context of document D25 as a whole, would realise that efficacy interference is a problem in dogs (see point 35), and also that no explanation (see point 36)

or experimental evidence (see points 39 and 40) supporting the statement on page 9 is provided in document D25.

42. In this context, the board considers that it is also not derivable from document D25 that interference is caused by the *B. bronchiseptica* component and not by any other component, as suggested by the respondents. There is no explicit statement to this effect in document D25 and no interference studies with the *B. bronchiseptica* p68 antigen were carried out either. There is thus no disclosure that *B. bronchiseptica* is the cause of the interference problem in document D25.

43. In the board's view, the skilled person would therefore have at least some doubts that the combination vaccine of document D25 comprising amongst other canine pathogens also *L. bratislava,* can indeed protect dogs against infection caused by *L. bratislava* (i.e. have the therapeutic effect mentioned in the claim). The fact that document D25 mentions a combination vaccine also comprising *L. bratislava* is therefore not considered to also directly and unambiguously disclose the therapeutic effect of protecting dogs against infection caused by *L. bratislava*.

44. In the board's view, the respondents' lines of argument based on the successful use of a *L. bratislava* bacterin in pigs or on vaccine compositions comprising cell preparations of *Leptospira* serovars other than *L. bratislava* are not persuasive for the following reasons.

45. As set out above, the skilled person's doubts about the protective effect of the combination vaccine of document D25 arise from the fact that interference is a

problem connected to the use of combination vaccines in dogs which is caused by "*some peculiarity of the canine biological system, or due to the reaction of the antigens with the canine biological system*" (see document D25, page 2, lines 36 to 38). Accordingly, the successful use of *L. bratislava* bacterin in pigs, i.e. an animal other than dog, does not allow any conclusion regarding the protective effect of a multivalent vaccine comprising L. *bratislava* in dogs.

46. Moreover, since efficacy interference depends on the antigens present in the combination vaccine (see point 32), the existence of effective combination vaccines comprising different combinations of antigens, e.g. *L. icterohaemorrhagiae and L. canicola,* as disclosed in document D42 does not allow any conclusion as regards the protective effect provided by the multivalent vaccine disclosed in document D25 either. The skilled person would have realised that this multivalent vaccine needed to be tested to determine whether or not it provided protection for all of the pathogens it includes.

47. The board further considers that decision T 578/06 does not support the respondents' case. In that decision, the board, when assessing inventive step, considered that "*in the absence of any formulated substantiated doubt*" the disclosure of experimental data or results in the application as filed and/or post-published evidence was not always required to establish that the claimed subject-matter solved the objective technical problem (see decision T 578/06 of 29 June 2011, Reasons, points 12, 13, 17, 18 and 19).

48. In the present case, novelty is at issue and not inventive step. According to established case law of

the boards of appeal, to be anticipatory a prior art document has to directly and unambiguously disclose the claimed subject-matter. Finally, as set out in point 43 above, there is doubt that document D25 in fact discloses a combination vaccine which protects against infection caused by *L. bratislava*.

49. The board concludes from the above that document D25 does not directly and unambiguously disclose that a combination vaccine, comprising *L. bratislava* amongst other canine pathogens, achieves the claimed therapeutic effect, i.e. protection of dogs against infection caused by *L. bratislava*.

50. Therefore, document D25 does not anticipate the subject-matter of claim 1 of the main request and *a fortiori* not of any other claim of the main request.

Document D18

51. Respondent II asserted that the paragraph bridging pages 7 and 8, as well as pages 8 and 9 and claims 1 to 3 of document D18 disclosed methods for protecting dogs against diseases caused by canine pathogens and multivalent vaccines which fell within the scope of the claims of the main request.

52. Document D18 relates to vaccine compositions for the oral vaccination of various animals. The paragraph bridging pages 7 and 8 discloses the preferred amount of a viral antigen to be administered in a dose of vaccine for a single animal, however, without specifying the nature of the antigen or the animal to be vaccinated.

53. On pages 8 and 9 of document D18, examples of bacterial and viral agents to be formulated into vaccines are disclosed in combination with the animals they infect. *L. bratislava* is listed among the agents infecting swine but is not listed as one of the agents infecting dogs (see page 8, lines 14 to 20, and page 9, lines 2 to 6, respectively). In other words, pages 8 and 9 do not disclose *L. bratislava* in connection with dogs, but only in connection with pigs.

54. Claim 1 of document D18 relates to a method of providing protection against diseases in an animal which comprises as step (b) the admixing of an antigen with the mixture of step (a). Dependent claim 2 further defines the method of claim 1 in that the "*antigen is capable of causing disease in an animal selected from the group consisting of swine, poultry, cattle, sheep, goats, horse, cat and dog*" while claim 3 further defines the method of claim 2, wherein the antigen is selected from a group consisting of more than 80 antigens, among them *Leptospira bratislava*. Accordingly, to arrive at the subject-matter of claim 1, the animal - dog - needs to be selected from a list in claim 2 and the antigen - *L. bratislava* - from a second list in claim 3. No pointer is provided in document D18 that would disclose that combination directly and unambiguously to the skilled person.

55. The board concludes from the above that the disclosure of document D18 does not anticipate the subject-matter of claim 1 of the main request and thus also not of any other claim of the main request.

Document D35

56. Respondent II further asserted that page 23, 5th full paragraph of document D35 disclosed a genetically modified *Bordetella* expressing a heterologous antigen, for use as a live attenuated vaccine for the treatment of dogs and that according to page 16, 2nd paragraph and claim 42 the heterologous antigen might be derived from *L. bratislava*.

57. Document D35 relates to the use of live attenuated and genetically modified *Bordetella* as an antigen delivery system. It discloses various antigens, including *L. bratislava*, which may be in the form of whole heterologous proteins, or portions thereof (see page 16, lines 8 to 23). According to document D35 "*the animal can be a dog and protection is directed to prevention of kennel cough*" rather than to an infection caused by *L. bratislava* (see page 23, lines 28 to 29).

58. Claim 40 of document D35 discloses a live mucosal antigen-delivery vector comprising a genetically engineered *Bordetella* expressing a heterologous antigen and claim 42 further defines the heterologous antigen to be derived from an agent selected from a group which includes *L. bratislava* amongst others. Therefore, the board concludes that document D35 discloses neither a *Leptospira* cell preparation as defined in claim 1, nor the use of such a preparation to protect dogs against infection caused by *L. bratislava*.

59. The disclosure of document D35 does not anticipate the subject-matter of any claim of the main request.

Conclusion on novelty (Article 54 EPC)

60. The board concludes from the above that the subject-matter of the claims of the main request is not anticipated by the disclosure of any of documents D25, D18 and D35.

61. The set of claims of the main request thus meets the requirements of Article 54 EPC. The appeal is allowable.

Remittal (Article 111(1) EPC)

62. Pursuant to Article 111(1) EPC the board may either exercise any power within the the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. It is the primary function of an appeal to give the losing party an opportunity to obtain judicial review on whether the decision appealed was correct.

63. The opposition division's decision only relates to the issues of added subject-matter and novelty and not to the further issues of sufficiency of disclosure and inventive step. The board indicated in a communication pursuant to Article 15(1) RPBA that it intended to remit the case to the opposition division for further prosecution should it find the appeal allowable. The parties did not request that the board also decide those issues not yet decided by the opposition division. Accordingly, the board remits the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution on the basis of the set of claims of the main request filed in the oral proceedings before the board.

The Registrar: The Chair:

S. Lichtenvort M. Blasi

Decision electronically authenticated