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Datasheet for the decision of 9 July 2021

Case Number: T 0230/18 - 3.3.04

Application Number: 11720079.0

Publication Number: 2569007

IPC: A61K39/02

Language of the proceedings: EN

Title of invention:
Vaccine against Mycoplasma hyopneumoniae, suitable for administration in the presence of maternally derived antibodies

Patent Proprietor:
Intervet International B.V.

Opponent:
Laboratorios Hipra, S.A.

Headword:
Vaccine against Mycoplasma hyopneumoniae/INTERVET

Relevant legal provisions:
EPC Art. 54
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:
Late-filed request - main request admitted (no)
Novelty - auxiliary request (no)

Decisions cited:
T 0158/96, T 1859/08, T 2506/12, T 0148/15, T 0239/16

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0230/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 9 July 2021

Appellant: (Patent Proprietor)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Hertford Road Hoddesdon, Hertfordshire EN11 9BU (GB)
Respondent: (Opponent)	Laboratorios Hipra, S.A. Avda. La Selva, 135 17170 Amer (ES)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 29 November 2017 revoking European patent No. 2569007 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	B. Claes
Members:	A. Chakravarty
	R. Romandini

Summary of Facts and Submissions

I. An appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent No. 2 569 007, entitled "*Vaccine against Mycoplasma hyopneumoniae, suitable for administration in the presence of maternally derived antibodies*".

II. In the decision under appeal, the opposition division considered a main request and an auxiliary request. It held that the subject-matter of claim 1 of the main request and of auxiliary request 1 lacked novelty over the disclosure in documents D24 (WO 94/07531) and D25 (WO 03/003941).

III. With the statement of grounds of appeal, the appellant submitted sets of claims of a main request and four auxiliary claim requests.

Claim 1 of the main request (which was to the main requests considered by the opposition division) reads:

" 1. A vaccine comprising inactivated *Mycoplasma hyopneumoniae* bacteria, for use in a method to actively protect an animal that has maternally derived antibodies directed against *Mycoplasma hyopneumoniae* against a disorder arising from an infection with *Mycoplasma hyopneumoniae*, by intradermal application of the vaccine, wherein the vaccine induces active protection after a single vaccination".

Claim 1 of auxiliary request 3, which was newly filed, differs from the above claim in that the word "bacteria" is replaced by the word "antigens".

IV. With their reply to the statement of grounds of appeal, the opponent (respondent) requested that auxiliary requests 2 to 4 not be admitted into the proceedings.

V. The following documents are referred to in this decision.

D1: WO 2006/113373

D3: WO 2007/103042

D11: Jones et al. (2005), "*Intradermal vaccination for Mycoplasma hyopneumoniae*", Journal of Swine Health and Production, 13(1), 19-27.

D24: WO 94/07531

D25: WO 03/003941

D33: Experimental Report of Dr M.H Witvliet dated 9 October 2017; "*Efficacy Of One-Dose Mycoplasma Hyopneumoniae Vaccines*".

D36: Atkinson *et al*. MMWR (February 8, 2002), General Recommendations on Immunization; Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP)

D37: MMWR (January 14, 1983), Recommendation of the Immunization Practices Advisory Committee General Recommendations on Immunization.

D38: Jones *et al*. (2007), Regulatory requirements for vaccine authorisation; Rev. Sci. Tech. Off. Int. Epiz., 2007, 26 (2), 379-393.

VI. The board issued a communication pursuant to Article 15(1) RPBA setting out its non-binding preliminary appreciation of the appeal.

VII. With a letter of 3 May 2021, the appellant withdrew auxiliary requests 1, 2 and 4. Auxiliary request 3 became the main request and the former main request became auxiliary request 1 (see section III). The appellant also submitted five documents including D36 to D38.

VIII. The arguments of the appellant relevant to the decision can be summarised as follows:

Main request
Admittance(Article 12(4) RPBA 2007)

The request had been filed with the statement of grounds of appeal and was convergent with those filed in the proceedings before the opposition division and was very similar to the former main request. Moreover, it was a mere combination of requests presented in the opposition proceedings.

The request had not been filed in the proceedings before the opposition division because it would have had no prospect of being held allowable in view of the fact that the opposition division had already held the subject-matter of claims having the separate amendments, which were now combined in a single claim, to lack novelty.

Auxiliary request 1 - claim 1

Novelty (Article 54 EPC)

Neither document D24 nor document D25 clearly and unambiguously disclosed the claimed subject-matter.

The claim was "*a second medical use claim, restricted to an effective treatment against a disorder arising from an infection with Mycoplasma hyopneumoniae by intradermal application of inactivated M. hyo bacteria (bacterin) vaccine in a single vaccination. For prior art to be novelty destroying, it is consistently required that the prior art clearly and unambiguously describes the efficacy of the intended use*".
In the present case, the active protection against a disorder arising from an infection with *Mycoplasma hyopneumoniae* (M. hyo) was a feature of the claimed subject-matter and "*there should be a direct and unambiguous disclosure of an intradermal vaccine being an effective vaccine*" in the cited documents. This teaching was completely absent.

It was the consistent case law of the Boards of Appeal that, in order for the subject-matter of a second medical use claim to lack novelty, the therapeutic efficacy had to be directly and unambiguously disclosed in the state of the art. This case law was reflected in the Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, I.C.4.1 and in decisions T 158/96, T 1859/08, T 2506/12, T 148/15 and T 239/16). For example, in decision T 148/15 (reasons, point 43) it was held that a particular disclosure in a document was not detrimental for the novelty of claimed subject-matter because the skilled person would have had at least some doubts that the relevant combination

vaccine that was disclosed would have the therapeutic effect mentioned in the claim. Thus, the case law provided that in case there was some doubt, a disclosure was not anticipatory.
The opposition division had failed to apply this case law for either document D24 or D25, stating only that the therapeutic efficacy disclosed therein was plausible. However, plausibility or probability had no place in deciding novelty. Instead, the opposition division had completely disregarded the requirement that the efficacy of an intradermally administered vaccine should be directly and unambiguously disclosed in documents D24 or D25, which it was not.

Although document D24 disclosed all the features of the claimed subject-matter in combination, it did not directly and unambiguously disclose that vaccination via the intradermal route was effective. It was evident that in document D24, protection against M. hyo after intradermal application of a vaccine was not tested for. Thus, there was no disclosure of the effective medical treatment claimed, i.e. effective protection after intradermal application of the vaccine. Document D24 did not even report the testing for any clinical signs of protection but merely measured and reported immune system parameters after a challenge of twice vaccinated piglets. Measuring the triggering of the immune system was not equivalent to the measuring clinical signs, such as protection against occurrence of lung lesions.

As was the case for document D24, document D25 did not deprive the claimed medical use of novelty because it did not contain any data about the medical effect achieved when using intradermal application of an inactivated M. hyo vaccine.

There remained a certain residual doubt as to whether the claimed therapeutic effect would in fact be achieved. Indeed, document D25 disclosed intradermal vaccination as one item in an arbitrary list (see page 10) containing options which could not work, e.g. oral administration of bacterins or the transdermal application (simple application of the vaccine on the skin) which was unlikely to work. The skilled person reading this list would have ignored it as it contained options that were clearly not effective.

Thus, document D25 therefore lacked a direct and unambiguous disclosure of an intradermally administered vaccine based on a bacterin. Document D24 also disclosed several different types of antigens (see grounds for the decision 2.8). The fact that Respisure (a commercial vaccine comprising a bacterin) was disclosed as being preferred did not mean that that it would be also useful for intradermal administration.

Moreover, both documents D3 and D33 provided consistent evidence, in line with other trials, that intramuscular administration (exemplified in documents D24 and D25) was considered better than intradermal administration. In contrast, the opposed patent showed that in piglets having a substantial amount of maternally derived antibodies, the intradermal route of administration performed significantly better in a one-shot vaccination program using a bacterin, than intramuscular administration. Indeed, it belonged to the common general knowledge of the skilled person, as illustrated in documents D36 to D38, that changing the route of administration (like the specific site of administration) might result in inadequate protection and/or increase adverse reactions. Hence, the skilled person would not simply expect intradermal

administration to be an efficacious route of administration merely because intramuscular administration was known to be efficacious.

The skilled person's doubt was amplified in view of the fact that, as could be seen from documents D1, D3, D11, D19 D27, D29 and D30, a vaccine for intramuscular administration could not be used in the same way for intradermal administration because only 10-20% of the volume was needed for intradermal in comparison to intramuscular administration. This supported the view that, when changing the route of administration in either document D24 or D25, the choice of alternative route of administration was completely open, intradermal administration being merely one of a number of choises.

Finally, the argument concerning the skilled person's residual doubt that disclosure in documents D24 and D25 of the presently claimed therapeutic effect was direct and unambiguous, was not an argument that the disclosure in these documents was lacked sufficiency of disclosure in analogy with the provisions set out in Article 83 EPC. In fact, it was not intended to argue that the disclosure in documents D24 and D25 was insufficient.

In view of the above, the disclosure in documents D24 and D25 did not anticipate the claimed subject-matter.

IX. The respondent's arguments relevant to the decision can be summarised as follows:

Main request
Admittance (Article 12(4) RPBA 2007)

Documents D24 and D25 and the corresponding novelty attacks were submitted with the respondent's submission dated 3 August 2017, after the opposition division had issued its preliminary opinion. The appellant should thereafter have submitted auxiliary claim requests addressing the objections raised in view of these documents. However, they did not do so, either in writing or during the oral proceedings before the opposition division. Instead, they deliberately decided to replace the feature "antigens" by "bacteria" in the previous main request and not in the previous auxiliary request 1, which contained the additional limitation "wherein the vaccine induces active protection after a single vaccination".

The main request should therefore not be admitted into the appeal proceedings.

Admittance of documents D36 to D38 and the associated line of argument (Article 13(2) RPBA)

With the submission dated 3 May 2021, the appellant submitted documents D36 to D38, allegedly reflecting the common general knowledge that the site of administration was a critical factor for vaccine efficacy and safety and put forward a line of argument that the skilled person would, in view of the differences between intradermal and intramuscular administration, have had doubts as to the efficacy vaccination by the former route.

These documents constituted new facts and in combination with the associated argument represented an

amendment to the appellant's case. In accordance with Article 13(2) RPBA 2020, such an amendment should, in principle, not be taken into account unless there were exceptional circumstances, justified by cogent reasons. However, no justification for any exceptional circumstances had been submitted.

Thus, documents D36 to D38 and the associated line of argument should not admitted into the appeal proc eedings.

Auxiliary request 1 - claim 1
Novelty (Article 54 EPC)

The appellant had conceded that documents D24 and D25 disclosed the claimed subject-matter. This disclosure was explicit.

The decisions referred to by the appellant were not pertinent for the case at hand because they addressed the question of whether a therapeutic effect of pharmaceutical composition was implicitly disclosed in a prior art document in cases where the document in question contained no relevant experimental evidence. In contrast, document D25 disclosed data demonstrating the disclosed therapeutic effect, i.e. protection of an animal having maternally derived antibodies against an M. hyo infection after a single dose.

By way of illustration, decision T 148/15 concerned claims directed to a vaccine composition for use in immunising dogs against infection caused by *Leptospira bratislava* comprising a cell preparation of *Leptospira bratislava* and a carrier. The board held that a cited document did not explicitly state the technical effect that a multivalent vaccine comprising an inactivated

cell preparation of *L. bratislava* was useful in protecting dogs against a diseases caused by *L. bratislava* and some passages in that document cast doubt on whether the effect of protecting dogs against infection caused by *L. bratislava* was attained. The board thus concluded that the therapeutic effect of the claimed subject-matter was not directly and unambiguously disclosed in the cited document.

In contrast, in the case at hand, the claimed therapeutic effect was explicitly and unambiguously disclosed in document D25 and the document did not cast any doubt regarding the explicitly described therapeutic effect.

In order to be detrimental to novelty, the teaching in a document had to be reproducible, i.e. had to be able to be carried out by the skilled person (see Case Law of the Boards of Appeal, I.C.4.11).

A disclosure in a document of a plausible technical teaching that did not run counter laws of nature was *a priori* enabling, i.e. reproducible. A party could challenge this presumption if they showed that there were serious doubts about the reproducibility, substantiated by verifiable facts. The appellant had argued that teachings in documents D24 and D25 were not reproducible and thus bore the burden of proof to substantiate this. They had failed to do this and hence the disclosure in these documents fully anticipated the claimed subject-matter.

X. The appellant (patent proprietor) requested that
- the decision under appeal be set aside;
- the patent be maintained on the basis of the set of claims of the new main request (filed as auxiliary

request 3 with the statement of grounds of appeal), or alternatively,
- that the patent be maintained on the basis of the set of claims of auxiliary request 1 (re-submitted as the main request with the statement of grounds of appeal).

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeals comply with Articles 106 to 108 and Rule 99 EPC and are admissible.

Admittance of the main request (Article 12(4) RPBA 2007)

2. The board has the discretionary power to hold requests inadmissible if they could have been presented in the opposition proceedings (Article 12(4) RPBA (2007)).

3. The main request (see sections III and VI) was filed with the statement of grounds of appeal. The appellant did not dispute that the novelty objection which this claim request seeks to address had been made in the proceedings before the opposition division. However, they argued that this request had not been filed in the proceedings before the opposition division because it would have had no prospect of being held allowable. Indeed, the opposition division had already held the subject-matter of claims having the separate amendments, which were now combined in a single claim, to lack novelty.

4. In the board's view a claim in which two features which alone were not sufficient to establish novelty of

claimed subject-matter over the disclosure in a cited prior art document are combined, could potentially be novel. Thus, not filing the present claim request in the proceedings before the opposition division actually prevented the opposition division from assessing whether the combination of features of the claimed vaccine claim 1 rendered the claimed subject-matter novel over the disclosure in documents D24 and D25. The appellant's reason for not filing the claim request earlier is thus not persuasive.

5. In view of the above considerations, the board decided not to take the set of claims of the main request into account in the appeal proceedings.

Admittance of documents D36 to D38 and the associated line of argument (Article 13(2) RPBA)

6. During the oral proceedings, the board considered the admittance of the general argument as presented in the statement setting the grounds of appeal on disclosure and the specific argument relating to intradermal administration as submitted by the appellant in response to the board's preliminary opinion, together with supporting documents D36 to D38 (see section VI.). In the board's view, the latter arguments, in particular those referring to documents D1, D3, D11, D17 and D19 as evidence purported to demonstrate why the skilled person would have had residual doubts about whether the therapeutic effect mentioned in the claim could be achieved and those arguments concerning the differences in volume of vaccine used for intradermal and intermuscular injection, clearly go beyond a mere reference to the skilled person's common general knowledge. Therefore, according to the board, they constituted an amendment of the appeal case, which

without the presence of exceptional circumstances, justified with cogent reasons by the party concerned, should not be taken into account (Article 13(2) RPBA). The appellant did not make the case that such exceptional circumstances existed. Consequently, the board did not admit these new submissions into the proceedings.

7. With respect to the admittance of documents D36 to D38, the board took no separate decision on this. In any case, these documents played no role in the board's final decision.

Auxiliary request 1 - claim 1

Novelty (Article 54 EPC)

8. Document D24 discloses a vaccine comprising inactivated *Mycoplasma hyopneumoniae* antigens (see claims 1 to 4) for vaccinating newborn piglets. It also discloses that the pregnant sows (or sows prior to breeding, to which piglets were subsequently born) are immunised with *Mycoplasma hyopneumoniae* antigens leading to the piglets having maternally derived antibodies (see page 10, second paragraph). Suitable routes of administration of the vaccines are disclosed on page 14, second paragraph. Intradermal application is mentioned in a single list of four specifically named conventional administration routes. A specific combination of elements requiring the selection of elements from a single list of alternatives is regarded as disclosed in the art and so does not fulfill the novelty requirement (c.f. Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, I.C.6.2).

9. Document D25 discloses the inoculation of 1 week old piglets with an the inactivated preparation of *Mycoplasma hyopneumoniae* (also referred to as bacterin, see page 3, line 37) RESPISURE-1 (cf. claim 5 and higher ranking claims). Claim 8 of document D25 refers to intramuscular administration. Thus, the disclosure in claim 2 of document D25 in combination with the disclosure on page 10, lines 14 to 17, disclosing intradermal administration as follows "*administration can be achieved by known routes, including the oral, intranasal, mucosal topical, transdermal, and parenteral (e. g., intravenous, intraperitoneal, intradermal, subcutaneous or intramuscular) [...]*" anticipates the claimed subject-matter. The claimed subject-matter is also disclosed in the section "*Dosing and Modes of Administration*" (see pages 9 to 10 of document D25).

10. At the oral proceedings before the board, the appellant did not dispute that the claimed subject-matter was disclosed in documents D24 and D25. However, they submitted that this disclosure left at least a residual doubt in the mind of the skilled person that vaccination via the intradermal route would be effective at producing a protective immune response, which was a feature of the claimed subject-matter. The result of the residual doubt was that the therapeutic effect, which was a feature of the claimed subject-matter, was not directly and unambiguously disclosed.

11. It is established in the case law that, for a disclosure in a document to be detrimental to the novelty of claimed subject-matter, its teaching has to be reproducible, i.e. it can be carried out by the skilled person (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, I.C.

4.11). At the oral proceedings before the board, the appellant explicitly stated that they did not object to the reproducibility of the disclosure in either document D24 or D25.

12. Under these circumstances, the board sees no reason to doubt that the disclosures in documents D24 and D25 concerning the therapeutic effectiveness of a vaccine as claimed administered by intradermal application, is reproducible and can be carried out by the skilled person.

13. In relation to the line of argument that there was no direct and unambiguous disclosure of the therapeutic efficacy of the vaccination by the intradermal route disclosed in documents D24 and D25 because there existed a residual doubt that this effect was in fact achieved when the vaccine was administered intradermally, the board has not been able to identify support in the case law for this approach to assessing novelty and is of the view that it is not correct.

14. The appellant has referred to five decisions allegedly supporting their view on how novelty was to be assessed in the case of a claim directed to a second or further medical use, where attaining the therapeutic effect was a functional feature of the claim.

15. However, in contrast to the present case, in decisions T 158/96, T 1859/08 and T 2506/12 the competent boards dealt with cases where the cited prior art document disclosed that a compound was undergoing phase II clinical trials and held that the fact that a compound is undergoing phases II clinical trails does not amount to evidence of that compound's clinical effectiveness. Thus, these decisions concern cases where the cited document does not explicitly disclose the relevant

therapeutic effect for the compound in question. Thus, these cases do not support the appellant's view.

16. Similarly, in decision T 148/15, the board held that a document disclosing 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* did not directly and unambiguously disclose the protection of dogs against infection caused by *L. bratislava,* i.e. have the therapeutic effect mentioned in the claim (see reasons 26 to 50). In contrast to the case at hand, the question to be answered was whether, in the absence of an explicit disclosure, the cited document disclosed the claimed therapeutic effect implicitly. Also in decision T 239/16, the board considered a situation where, in contrast to the present case, the cited document did not explicitly disclose the therapeutic effect mentioned in the claim at issue. Thus, these cases also does not support the appellant's view.

17. In view of the above considerations, the board concludes that the claimed subject-matter is disclosed in both documents D24 and D25 and hence is not novel (Article 54 EPC).

18. Thus, no admitted claim request is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated