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Datasheet for the decision of 15 October 2024

Case Number: T 0083/23 - 3.3.04

Application Number: 15726586.9

Publication Number: 3148576

IPC: A61K39/09, C12N9/50

Language of the proceedings: EN

Title of invention:
Vaccine composition against Streptococcus suis infection

Patent Proprietor:
Ceva Santé Animale S.A.

Opponent:
Intervet International B.V.

Headword:
S.suis/CEVA

Relevant legal provisions:
EPC Art. 100(a), 100(b), 56, 108
Arrangements for deposit accounts, points 7 and 10.3, Supplementary publication 3, OJ EPO 2022

Keyword:

Grounds for opposition - insufficiency of disclosure (no) - inventive step (yes) - ex post facto analysis
Appeal of the opponent deemed not filed - appeal fee

Decisions cited:

G 0002/97, G 0001/03, G 0001/18, T 0292/85, T 0079/01, T 0609/02, T 1797/09, T 0895/13, T 2620/18, J 0008/19, T 0317/19, T 0703/19, T 0444/20

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Case Number: T 0083/23 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 15 October 2024

Appellant: (Patent Proprietor)	Ceva Santé Animale S.A. 10 avenue de la Ballastière 33500 Libourne (FR)
Representative:	Plasseraud IP 104 Rue de Richelieu CS92104 75080 Paris Cedex 02 (FR)
Respondent: (Opponent)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 18 November 2022 concerning maintenance of the European Patent No. 3148576 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	D. Luis Alves
	A. Bacchin

Summary of Facts and Submissions

I. European patent No. 3 148 576, entitled "*Vaccine composition against Streptococcus suis infection*", was granted on European patent application No. 15 726 586.9, filed as an international application published as WO 2015/181356.

The patent was granted with six claims. Claim 1 reads:

"1. A vaccine composition for use in the prophylactic, metaphylactic or therapeutic treatment of a *Streptococcus suis* infection in pigs comprising an effective amount of at least one polypeptide selected from the group of
(a) a protein designated IdeSsuis having the amino acid sequence of SEQ ID NO: 1, or
(b) a protein designated rIdeSsuis having the amino acid sequence of SEQ ID NO: 2, 6 or 7,
and at least a pharmaceutical carrier, a diluent or an adjuvant."

Claims 2 to 6 define more specific embodiments of the vaccine for use of claim 1. Claim 4 reads:

"4. The vaccine composition for use in the prophylactic, metaphylactic or therapeutic treatment of a Streptococcus suis infection in pigs according to at least one of claim [sic] 1 to 3, containing an overall amount of about 0.05-2 mg of protein"

II. The patent was opposed under Article 100(a) EPC, on the grounds of lack of inventive step (Article 56 EPC), and

under Article 100(b) EPC, on the grounds of insufficient disclosure.

III. Appeals were lodged by the patent proprietor and by the opponent against the opposition division's interlocutory decision that, account being taken of the amendments in the form of auxiliary request 3, the patent and the invention to which it related met the requirements of the EPC (Article 101(3)(a) EPC). In this decision, the board refers to the parties by their respective roles in the opposition proceedings.

IV. With their letter dated 3 February 2023, the opponent submitted arguments concerning the payment order for the appeal fee. Further, the opponent requested an appealable decision on the issue of payment of the appeal fee, and oral proceedings in the event of the board deciding that the appeal fee had not been validly paid. On the same date, the opponent filed a debit order for the appeal fee in an electronically processable format.

V. With their statement setting out the grounds of appeal, the patent proprietor filed sets of claims of auxiliary requests 1 and 2, respectively identical to auxiliary request 2 filed at the oral proceedings before the opposition division, and auxiliary request 3 held allowable by the opposition division. Further, they filed document D21.

VI. With their statement setting out the grounds of appeal, the opponent contested the opposition division's decision in respect of the inventive step of then auxiliary request 3.

VII. Both parties filed replies to the statements of grounds of appeal. With their reply, the opponent filed document D22.

VIII. With their letter dated 13 October 2023, the patent proprietor submitted further arguments.

IX. The board issued summons to oral proceedings to be held on 15 October 2024 and subsequently a communication pursuant to Article 15(1) RPBA.

X. With their letter dated 2 October 2024, the opponent submitted further arguments as well as document D23.

XI. Oral proceedings were held as scheduled. At the beginning of the oral proceedings, the opponent withdrew their request for a separate decision on whether their appeal was deemed to be filed.

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

D3: Declaration by A.A.C. Jacobs dated 17 June 2021

D5: Baums, C.G. *et al.*, Clinical and Vaccine Immunology 16(2), 2009, pages 200-208

D6: Seele, J. *et al.*, Journal of Bacteriology 195(5), 2013, pages 930-940

D10: Reine Vindebro, doctoral thesis - "Studies on secreted cysteine proteases of *Streptococcus pyogenes* - IdeS and SpeB", May 2014

D13: Rieckmann, K. *et al.*, Vaccine: X 3, 2019, pages 1-9.

D14: WO 2019/115741

D15: MSD Animal Health Experimental report by A. Jacobs and R. Grommen dated 1 July 2022

D16: Declaration by J-F Collin dated 8 September 2022

D18: WO 2021/185680

D19: Ceva Study report dated 2021

D20: Declaration by A.A.C. Jacobs dated 30 September 2022

D21: Goyette-Desjardins, G. *et al.*, Emerging Microbes and Infections 3(e45), June 2014, pages 1-20

D22: Willemse, N. *et al.*, Scientific Reports Nature Research 9(15429), 2019, pages 1-11

D23: Declaration by A.A.C. Jacobs dated 30 September 2024

XIII. The patent proprietor's arguments, where relevant to the decision, are as follows.

Filing of the opponent's appeal

The appeal fee was only paid after expiry of the relevant time limit and the appeal should be deemed not to have been filed. Indeed, the failure to file a debit order in an electronically processable format (xml) inevitably led to its invalidity.

Main request (patent as granted)
Disclosure of the invention (Article 100(b) EPC)

Claim 1 defined a "first medical use". Indeed, the patent showed for the first time the usefulness of protein IdeSsuis in general, and claim 1 did not specify a therapeutic effect against the strain of serotype 9 sequence type (ST) 16 used by the opponent in documents D3 and D15.

Such a technical effect would be taken into account for the purposes of assessing sufficiency of disclosure only if set out in the claim (Case Law of the Boards of Appeal of the EPO, 10th ed. 2022 (CLBA), II.C.3.2.). This was not the case, however.

Moreover, to fulfil the requirements of sufficiency of disclosure it was not required to demonstrate the efficacy of the protein against all serotypes, and all STs of each serotype. On the other hand, the results in the patent were not contested by the opponent.

Furthermore, even the existence of non-responders was not a reason to deny sufficiency of disclosure (see decision T 421/14). In any event, the lack of protection against serotype 9 infection had not been demonstrated because, in order to demonstrate the lack of an effect, it is necessary to select the optimal experimental conditions, including the relevant controls and a wide range of protein amounts. As regards document D3, the experiments used too small an amount of protein, so much so that even a vaccine composition with protein derived from serotype 9 did not confer protection against the test strain of serotype 9. As regards document D15, the controls were not suitable because the small number of dead animals

(4/12) in the control group meant that it was not possible to demonstrate a decrease in those numbers with vaccination (see declaration D16).

On the other hand, document D14 showed that a dose of 230 µg protein did indeed provide heterologous protection (see example 2). These experiments used a strain of the same serotype and ST as those in documents D3 and D15.

The opponent's argument required some of the results to be considered accurate, as in documents D15 and D3, and some to be considered inaccurate, as in document D14.

Document D13, with its dose of 400 µg protein, also confirmed heterologous protection.

Inventive step (Articles 100(a) and 56 EPC)

The closest prior art was represented by document D5. However, even if document D6 were taken to represent the closest prior art, the claimed subject-matter still involved an inventive step. It differed therefrom in the use of IdeSsuis as a vaccine and the objective technical problem was "the provision of an efficient protective subunit vaccine able to prevent *Streptococcus suis* infection in pigs".
The solution was not obvious from documents D6 or D10.

The opponent constructed artificial closest prior art, using hindsight to select passages of documents D5, D6 and D10 and combine them in light of the patent. The purpose of the patent was not addressed in document D6 but instead in document D5.

By selecting a document directed at the identification of IdeSsuis as the closest prior art, the opponent formulated the objective technical problem with inappropriate hindsight.

This document disclosed that IdeSsuis specifically cleaved IgM in pigs and could be involved in immune escape of *S. suis*. However, it did not suggest that IdeSsuis induced opsonising antibodies against *S. suis*. The passage on page 939 stated instead that inhibiting the activity of IdeSsuis could improve the protection obtained with another vaccine, such as a bacterin vaccine.

The skilled person would not have looked for a solution in document D10, which was published shortly before the relevant date of the patent and did not relate to *S. suis* vaccines but instead to IgG proteases, thus with a different function and only low similarity to IdeSsuis. The opponent made a link between point 1.4.11, which mentioned IgG, and point 1.4.12, which mentioned *S. suis*, but this link was not made in the document itself. Document D6 also disclosed that IdeS homologues in other bacteria had different functions and only low similarity (see page 933, left-hand column). The fact that document D10 cited document D6 was not relevant either, because the skilled person would start from D6 and not from D10.

XIV. The opponent's arguments, where relevant to the decision are:

Filing of the opponent's appeal

The notice of appeal complied with the requirements of Article 108 and Rule 99 EPC. None of these provisions

required the accompanying letter to be in an electronically processable format (Form 1038E) for an appeal to be validly filed.

The intention to give the order to deduct the appeal fee was clear from the notice of appeal.

The principle of legitimate expectations had to be taken into account (see decision T 703/19). In application of this principle, the EPO was required to inform the opponent of the deficiency. However, the EPO did not do so until the period for paying the appeal fee had lapsed, despite having assessed the appeals before the end of said period, as apparent from the letter it sent to the parties indicating the start of the appeal proceedings.

Main request (patent as granted)
Disclosure of the invention (Article 100(b) EPC)

Claim 1 defined the therapeutic use broadly as protection against *S. suis* infection in pigs. Thus, the skilled person should be able to arrive at protection against infection by *S. suis* serotype 9 by using a protein of SEQ ID NO: 2. However, the data in documents D3 and D15 demonstrated that this protein did not confer protection against a strain of serotype 9 ST16. Strains of serotype 9 ST16 were of practical relevance.

Document D3 reported on the outcome of vaccinating pigs with doses of 4.4 µg (study 1), 50 µg (study 2) and 80 µg (study 3) of a protein of SEQ ID NO. 2. Despite using levels below those used in the examples in the patent, namely 250 µg, the results substantiated serious doubts that the therapeutic effect claimed was provided because the skilled person would have expected

protection at such doses for the following reasons: (i) for the skilled person a protein amount of 10 to 20 µg was common for swine vaccination; (ii) the doses of studies 2 and 3 were much higher than used in study 1, where just 4.4 µg in a single-dose vaccination protocol elicited almost 100% protection against homologous challenge; (iii) the patent showed that a higher protein dose was not necessary for heterologous protection than for homologous protection, since the same level of protection was achieved with the same dose for heterologous as for homologous challenge (see figure 3); (iv) in view of (iii), a dose of 50/80 µg was selected for studies 2 and 3 with the expectation that it would confer heterologous protection, since the much lower dose in study 1 conferred almost 100% homologous protection.

Reason (i) was also confirmed in (a) document D19 (see page 8), a study from the patent proprietor, in which a dose of 66 µg was expected to confer protection, based on serology; and (b) in the patent itself, which disclosed 50-2000 µg protein as a suitable range (see dependent claim 4). Indeed, the lack of heterologous protection in document D3 was not due to the use of a 50 µg dose (study 2) or 80 µg dose (study 3) versus a 250 µg dose in the patent, but rather to the use of a strain of ST16 within serotype 9.

Moreover, the doses used in studies 2 and 3 of document D3 showed an absence of heterologous protection despite two doses of the vaccine with total protein amounts 25 times those used in study 1 of the same document relating to homologous protection.

Although doses of 50 and 80 µg did not replicate example 2 of the patent, which used 250 µg, they were

nevertheless relevant to the issue of sufficiency of disclosure because they demonstrated a lack of heterologous protection at a dose specifically claimed in the patent. Indeed, claim 4, specifying a dose of 50 µg, referred back to claim 1, which specified a protein of SEQ ID NO: 2.

Document D15 reported the results of experiments using protein doses identical to those in the examples in the patent. However, it did not show even a tendency toward a protective effect against serotype 9 ST16 challenge.

Thus, the experimental results in documents D3 and D15 showed a consistent lack of heterologous protection. They related to experiments over a range of protein amounts (4.4 µg, 50µg, 80µg and 250 µg).

Document D14 was a patent application showing, in example 2, heterologous protection (at a substantially lower level compared to homologous protection). These results were a chance event and that patent application had been withdrawn.

The experimental results provided in documents D3 and D15 did not aim to contradict those in the patent. They aimed to show that embodiments of great practical relevance, and which were encompassed by the claims, could not be carried out by the skilled person. This was contrary to the requirements of Article 83 EPC that the patent provide the skilled person with the information to perform the invention, without undue burden, over substantially all the embodiments claimed, in particular also those defined in the dependent claims (see CLBA, II.C.3.1, see T 1011/01, point 2.3 of the Reasons). Due to the challenge strain used in the experiments in the patent, some heterologous protection

had been made credible. This, however, did not constitute a disclosure of a concept fit for generalisation based on the data in the patent (see CLBA, II.C.5.4, first paragraph).

Inventive step (Articles 100(a) and 56 EPC)

The closest prior art was represented by document D6. It disclosed research building on that disclosed in document D5. The latter could not represent the closest prior art because it showed low heterologous protection. However, it disclosed that this low protection derived from the failure to induce opsonising antibodies. In view of these conclusions in document D5, the skilled person would look for induction of opsonising antibodies. Since the aim of the invention was to provide a vaccine for heterologous protection, the skilled person would look rather at document D6, which addressed this issue and aimed at improving vaccines (see page 939, right-hand column, third paragraph). It suggested neutralising the IgM protease activity of protein IdeSsuis (see same passage).

The distinguishing feature with respect to this prior art was merely how to put into practice neutralisation of the IdeSsuis IgM protease activity. No technical effect had been shown over the whole scope of the claim. Accordingly, the objective technical problem was to be formulated as "how to arrive in practice at the neutralisation of the IgM protease activity".

The problem of providing heterologous protection was not solved over the whole scope claimed. If an opponent succeeded in casting reasonable doubt that the technical effect was achieved, the burden was on the

patent proprietor to demonstrate the technical effect it relied on. Casting reasonable doubt was a lower threshold than required, under the assessment of sufficiency of disclosure, to substantiate serious doubts (see T 1797/09). The opponent had met this threshold by casting reasonable doubt in relation to protection against strains of a highly prevalent serotype.

The solution to the above-formulated problem was the addition of IdeSsuis to the vaccine composition. This was obvious from document D6 on its own, since it merely amounted to testing a well-founded hypothesis.

The solution was also obvious from the disclosure in document D10. Indeed, homologues of IdeSsuis were already known from document D6 (see abstract and page 939, left-hand column, second paragraph).
Document D10 disclosed research which was a continuation of that in document D6. It showed that proteins of the IdeS protease protein family could be used as a vaccine (see point 1.4.11, second paragraph) and referred to "neutralisation". Although it did not mention heterologous protection, this was not necessary to render the claimed solution obvious because document D6 had already shown that protein IdeSsuis was present in serotypes 2, 5, 7 and 9 (see Figure 3 on page 934).
Moreover, the combination with document D10 was also obvious from the fact that D10 cited document D6.

XV. The requests of the parties were as follows.

The patent proprietor requested that the opponent's appeal be dismissed as not validly filed; further, that the patent be maintained in the form of the main

request (patent as granted) or, alternatively, as amended on the basis of the set of claims of auxiliary request 1 or auxiliary request 2, both filed with the statement setting out the grounds of appeal. The patent proprietor further requested that document D23, filed with the opponent's submissions of 2 October 2024, not be admitted into the appeal proceedings.

The opponent requested that the decision under appeal be set aside and the patent be revoked in its entirety. The opponent further requested that, if document D23 had to be relied upon, it be admitted into the proceedings.

Reasons for the Decision

Appeal of the patent proprietor

1. The appeal filed by the patent proprietor complies with Articles 106 to 108 and Rule 99 EPC and its admissibility was not contested.

2. The opposition division held, *inter alia*, that the invention as defined in the claims as granted was not sufficiently disclosed and that claim 1 of auxiliary request 2 related to subject-matter extending beyond the content of the application as filed. The patent proprietor contested these aspects of the decision under appeal.

Appeal of the opponent

3. In the present case, it was in dispute whether the opponent's appeal had been validly filed.

3.1 In accordance with Article 108 EPC, a notice of appeal must be filed within two months of notification of the decision and the relevant appeal fee must be paid. A notice of appeal is not deemed to have been filed until the fee for appeal has been paid (see also G 1/18, Headnote 1(a) and 2).

3.2 In the present case, the opponent filed a notice of appeal within two months of notification of the opposition division's decision. As to the appeal fee, an order to debit the opponent's deposit account was given in the notice of appeal, thus on paper rather than in an electronically processable format.

3.3 It is in dispute whether under the present circumstances a debit order was validly given within said time limit.

3.4 According to the arrangements for deposit accounts (ADAs), in the version applicable at the relevant time (point 7 ADAs, valid as of 10 September 2022, see Supplementary publication 3, OJ EPO 2022, highlighted by the board):

Debiting occurs only on the basis of an ***electronic debit order*** *signed by the account holder or the authorised representative. The signature may take the form of a text string signature, a facsimile signature, an enhanced electronic signature, or authentication with smart card if payment is made via Central Fee Payment (Point 7.1.1 ADA)*

The debit order must be filed in an electronically processable format (xml) via one of the following:
– EPO Online Filing using EPO Forms 1001E, 1200E, 2300E or 1038E, or Online Filing 2.0 using EPO Forms 1001E, 1200E or 1038E;

– EPO Online Filing or ePCT using the PCT fee calculation and payment feature, or Online Filing 2.0 using the PCT fee calculator and payment feature7 with Forms PCT/RO/101 and PCT/IPEA/401;

– Central Fee Payment (Point 7.1.2 ADA).

Debit orders submitted in any other way, e.g. on paper, by fax, via the EPO web-form filing service or using a different format such as a PDF attachment or the annotation field in the online forms, ***are invalid and thus will not be carried out****. The legal consequence of filing an invalid debit order is laid down in point 10.3. (Point 7.1.3 ADA).*

If a debit order is ***submitted via a non-accepted means of filing or in an invalid format, the date of receipt will not be regarded as the payment date****. If this means that a time limit for paying a fee has expired, the party to the proceedings may make use of any of the legal remedies available under the EPC or the PCT. (Point 10.3 ADA).*

3.5 The opponent argued that neither Article 108 nor Rule 99 EPC require the accompanying letter to be in an electronically processable format (Form 1038E) for an appeal to be validly filed. The intention to give the order to deduct the appeal fee was clear from the notice of appeal.

3.6 In the board's view, the debit order filed by the opponent on paper with the notice of appeal on 16 January 2023 was not validly filed. The filing of the debit order in an electronically processable format after expiry of the time limit of two months as set by Article 108 EPC, i.e. on 3 February 2023, was late, with the consequence that the opponent's appeal is deemed not to have been filed.

3.7 The argument that Form 1038E is mentioned in neither Article 108 nor Rule 99 EPC cannot stand. Where an opponent decides to avail itself of the use of a deposit account as a method for paying the relevant fees with the EPO (Article 5(2) Rules relating to fees), it is also its duty to know the relevant requirements for debiting a deposit account, including the types of debit orders and the accepted ways of filing them.

3.8 The opponent's reference to its clear intention to give the order to deduct the appeal fee is not relevant under the present circumstances either.

The relevance of a deposit account holder's intention, if any, may be taken into account in the context of the correction of errors under Rule 139 EPC. Despite the fact that in the present case no correction was expressly requested, and nor was the argument made that the filing of a debit order on paper was due to an error, the board points out that even regarding the opponent's arguments as an implicit request for correction, this cannot succeed. A correction of the debit order in application of Rule 139 EPC presupposes that a valid debit order exists, i.e. filed in an electronically processable format.

In the jurisprudence of the Boards of Appeal, correction of a debit order has only been allowed in case of errors concerning the amount of the appeal fee (see e.g.J 8/19 Reasons 2.4, T 317/19 Reasons 2.4.2, T 444/20 Reasons 2.4.3, T 2620/18 Reasons 5).

A correction cannot be allowed to "remedy" the non-existence of a debit order. In the present case, in the absence of a valid debit order, there is nothing which could be corrected within the meaning of Rule 139 EPC.

A correction cannot remedy ignorance of the applicable provisions either. In this context, after introduction of the requirement that debit orders have to be filed in an electronically processable format on 1 December 2017 (see Notice from the European Patent Office dated 27 September 2017, in Supplementary publication 5, OJ EPO 2017, page 2 and point 5.1.2 ADA in the same Supplementary publication), the ADAs, in the versions applicable in 2017 (cf. point 5.1.3, second sentence, ADA in Supplementary publication 5, OJ EPO 2017) and in 2019 (cf. point 5.1.3, second sentence, ADA in Supplementary publication 4, OJ EPO 2019), did indeed contain an indication that the EPO would, as a courtesy service, inform the party to the proceedings if the debit order had been submitted in an invalid format. However, this "courtesy service" was removed from the 2022 version of the ADAs (cf. point 7.1.3 ADA in Supplementary publication 3, 2022), which is the version applicable in this case. This confirms that by that time the requirement that debit orders be filed in electronically processable formats was considered settled.

Further, the opponent invoked application of the principle of protection of legitimate expectations and extensively relied on decision T 703/19.
However the circumstances underlying case T 703/19 are different: the debit order was actually filed in an electronically processable format, the only missing information being the ticking of the box on the method of payment; in addition, the then applicable ADA provisions still contained the indication that the EPO would inform the account holder as a courtesy service, if the debit order was submitted in an invalid format. The present ADA no longer contain a provision creating a legitimate expectation on the account holder that the EPO would draw attention to the deficiency.
As a matter of principle there is no obligation on a board to warn a party of deficiencies within the area of the party's own responsibility (see G 2/97, Headnote and e.g. T 79/01, Reasons 8). Responsibility for meeting the conditions for an admissible appeal cannot be devolved to the board of appeal. In the present case, however, it appears that the opponent has done so. It also did not consider it necessary to file a legal remedy, i.e. a request for re-establishment of rights, as a precautionary measure when it filed the debit order in the correct format after the relevant time limit expired. This was also a possible means, recommended in the above mentioned passage of the ADA (point 10.3).

3.9 In view of these considerations, particularly the history of the ADAs, the board concludes that it was incumbent on the opponent to know the relevant provisions for filing a valid debit order in order to pay the appeal fee (ignorance of the law is no excuse). Since the debit order was not filed in timely manner in the required format, the opponent's appeal was deemed

not to have been filed in line with the clarifications given in decision G 1/18.

Main request (patent as granted)
Disclosure of the invention (Articles 100(b) EPC)

4. Claim 1 is drafted in the form of a purpose-limited product claim, pursuant to Article 54(5) EPC, and is directed to a vaccine composition for use in the treatment of a *Streptococcus suis* infection in pigs (for the exact claim wording refer to point I. above).

5. In the Case Law of the Boards of Appeal, where a therapeutic application is claimed in the form according to Article 54(5) EPC, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, to fulfil the requirements of sufficiency of disclosure the suitability of the composition for the claimed therapeutic application must be derivable from the application, unless this is already known to the skilled person at the priority date (see T 609/02, point 9 of the Reasons and T 895/13 of 21 May 2015, points 3 to 5 of the Reasons).

6. At issue in the present appeal was whether heterologous protection was sufficiently disclosed, and more specifically protection against a strain of *S. suis* serotype 9 by means of a vaccine composition comprising a protein of SEQ ID NO: 2. This embodiment was encompassed by claim 1, which was not limited to protection against infection by *S. suis* strains of serotype 2.

7. The board has arrived at the conclusion that the experimental results in the patent make protection

against infection by strains of serotype 9 credible and that the experimental results submitted by the opponent are not suited to substantiating serious doubts.

The experimental results in the patent

8. The board agrees with the opposition division and with the parties that the results in example 2 demonstrate the suitability of a protein of amino acid sequence SEQ ID NO: 2 to confer protection against infection by strains of serotype 9, i.e. suitability for heterologous protection. In this example, the efficacy of a vaccine composition containing said protein was evaluated using a bactericidal assay. This involved determining the survival of *S. suis* bacteria of a given strain added to blood samples taken from animals to which the test vaccine had previously been administered. The animals were vaccinated in a prime-boost protocol, each dose containing 250 µg of the protein. The bactericidal assay was carried out with a strain of serotype 2 as well as with a strain of serotype 9. The results are presented in figure 3.

Heterologous protection against a strain of serotype 9

9. The opponent did not dispute that the experimental results in example 2 of the patent made protection against infection with a serotype 9 strain credible and instead submitted that, while this was the case for the specific strain used in example 2, it was not the case for the very relevant strain used in the experiments reported in documents D3 and D15.

10. Therefore, in the present case it was not at issue that the patent made the therapeutic effect in claim 1 credible. Rather it was argued that the evidence

submitted by the opponent substantiated serious doubts in respect of one of the embodiments encompassed by said claim.

Documents cited by the parties for evaluating protection against strains of serotype 9

11. The parties referred to documents D3 and D13 to D15. All were made available to the public only after the date of filing of the patent. They report experiments using a challenge strain of *S. suis* serotype 9, the strain being further classified within this serotype according to a sequence type (ST) which differs between the experiments as follows: while in the patent the strain belongs to ST99, in document D13 it belongs to ST94, and in documents D3, D14 and D15 to ST16.

12. In this context, the parties also made extensive submissions on whether or not strains of the serotype 9 sequence type ST16 were the most prevalent cause of *S. suis* infection in different geographical regions of the world. The opponent's argument was that this was a strain of great practical relevance. Documents D21 and D22, filed by the parties during the appeal proceedings, were only cited in this context. However, the board's reasoning below applies irrespective of the prevalence of ST16 strains. Therefore, this question does not need to be addressed in order to reach a decision. The opponent's arguments relating to this strain were that protection could not be obtained against the test strain of serotype 9 ST16 when the vaccine contained serotype 2 protein at 50 or 80 µg (citing document D3) or 250 µg (citing document D15). These arguments are considered below in turn.

The experimental results in documents D13 and D14

13. It was not contested that document D13 discloses a vaccine composition containing a protein having the amino acid sequence of SEQ ID NO: 2. Animals were vaccinated in a prime-boost protocol, each dose containing 400 µg of the protein. The efficacy of the vaccine composition against infection by a serotype 9 strain was evaluated by bactericidal assay, seroconversion and animal survival to challenge. The vaccination induced seroconversion in 13 out of 20 pigs, significantly reduced the values in the bactericidal assay and resulted in all the animals surviving the challenge, compared to 89% mortality in non-vaccinated animals (see abstract). It was also not disputed that the results demonstrate the suitability of the protein of SEQ ID NO: 2 for protecting against infection by the serotype 9 challenge strain used.

14. However, the opponent argued that these results cannot show suitability to confer protection against infection over all embodiments encompassed by claim 1 because the amount of protein (400 µg) used in these experiments was higher than that used in example 2 of the patent (250 µg).

15. The board does not find this argument convincing for the following reasons. The teaching in the patent is not limited to heterologous protection with protein in a dose of 250 µg and the amount used in document D13 falls within the range taught in the patent, namely 50 to 2000 µg (see claim 4).

16. Therefore the board concludes that document D13 confirms that the protein is suitable to confer protection against a further, different strain of

serotype 9, albeit requiring a higher amount of protein than in example 2 of the patent.

17. Also as regards document D14, it was not contested that the vaccine composition in example 2 contains a protein rIdeSsuis from serotype 2 and having the amino acid sequence of SEQ ID NO: 2. Animals were vaccinated in a prime-boost protocol, each dose containing 230 µg of the protein. The efficacy of the vaccine composition was evaluated *inter alia* by an average clinical score and by survival to challenge. The conclusion in this example states that the protein "*induces protection against* S. suis *serotype 9 challenge. This was demonstrated by a reduction in clinical scores, the number of animals reaching the humane endpoint, and the number of animals from which challenge bacterium could be reisolated from the blood*."

18. The opponent argued that these results showed heterologous protection at a substantially lower level compared to homologous protection, that they were a chance event and that this patent application had been withdrawn.

19. As regards efficacy for heterologous protection versus homologous protection, the board finds the argument unconvincing both in view of the results presented in the document and in view of the conclusions drawn therein, which seem fully consistent with the results. The results include the following: an average clinical score 19 versus 43 for vaccinated animals versus control, and mortality rate 4/10 versus 9/10 animals respectively in the challenge with serotype 9, as compared with 11 versus 61 and 1/9 versus 10/10 for the same parameters in the challenge with serotype 2. The conclusions drawn, which were partly quoted in

point 17. above, that the the protein induces protection against *S. suis* serotype 9 challenge, are thus supported by the results.

20. The opponent alleged that these results were merely a chance event. Agreeing with this argument would amount to disregarding them. The board does not see any basis on which to disregard this document. The mere fact that the patent application has been withdrawn cannot, in the absence of any further indications/evidence, allow a conclusion that the results were indeed a mere chance event, nor is this derivable from document D14 on its own (see point 33. below).

21. In summary, the board is of the view that documents D13 and D14 each confirm the disclosure in the patent that the protein of amino acid sequence SEQ ID NO: 2 is suitable for heterologous protection.

The experimental results in document D3

22. This document describes three studies. Study 1 concerns homologous protection and thus is of no further relevance to the present issue. Studies 2 and 3 concern protection conferred by a protein having amino acid sequence SEQ ID NO: 2 against challenge with a strain of serotype 9 ST16. They differ in the amount of protein used for vaccination, 50 µg and 80 µg respectively. The efficacy of the vaccine composition was evaluated *inter alia* by an average clinical score and by survival to challenge. The conclusion states that, since there were no significant differences between the vaccinated and non-vaccinated groups, the protein did not provide protection against the challenge strain.

23. According to the opponent, these results demonstrate that the protein did not confer protection against a strain belonging to ST16 within serotype 9. The discrepancy with the results in example 2 of the patent was attributed to the different strain used.

24. However, studies 2 and 3 on which the opponent relies use approximately 4 to 5 times less protein than example 2 of the patent. Accordingly, given the smaller amount of the protein in the vaccine, it cannot be concluded that any lack of protection is due to the specific strain used in the challenge experiment. The opposition division noticed this deficiency but nevertheless referred to document D3 when it held that there were serious doubts regarding protection against infection by serotype 9 strains. However, in view of the dose used, the board is convinced that the evidence provided by the opponent in the form of document D3 is not suitable for substantiating serious doubts that a protein of amino acid sequence SEQ ID NO: 2 is able to confer protection against infection by a strain of *S. suis* serotype 9 ST16.

25. The opponent argued that the lower dose does not prevent this conclusion from being drawn. Several arguments were presented as to why, in view of the experimental results and commonly used doses in pig vaccination, a dose as low as 50 µg would have been expected to provide protection. Document D19 was cited in this context. In the board's view, if serious doubts are to be substantiated in a case such as this, where the therapeutic effect is made credible based on the results in the patent, it is not enough to argue why a lower dose would be expected to provide protection for a given strain, and then extrapolate this to a different strain, without testing the doses actually

used in the example in the patent. The patent does not teach such extrapolation, nor does it teach that the dose is irrelevant or that identical doses would apply irrespective of the challenge strain or amino acid sequence of the protein in the vaccine.

26. In a further line of argument, the opponent submitted that a dose of 50 µg of protein should attain the therapeutic effect because this amount is recited in dependent claim 4 and is thus a specifically claimed embodiment.

27. This argument is not convincing for the following reasons. Claim 4 refers back to claim 1 and defines a protein amount in the range from 50 to 2000 µg. It thus discloses an amount of 50 µg protein as the lower end of the range. However, claim 1 does not specifically combine a vaccine containing a protein of SEQ ID NO: 2 with protection against infection by serotype 9 strains, nor does it link such a combination to the specific amount of 50 µg from the range in claim 4. Therefore, an embodiment corresponding to the experiment in document D3, namely a vaccine comprising 50 (or 80) µg protein of the amino acid sequence SEQ ID NO: 2 for protection against a strain of serotype 9 ST16, is not specifically defined in claim 4.

28. Despite not reproducing example 2 of the patent, document D3 demonstrates that protein SEQ ID NO: 2 at a dose of 50 µg did not achieve protection against a strain of serotype 9 ST16. The question that remains to be addressed is the impact of this embodiment that is not specifically claimed but is encompassed by claim 1 on the assessment of sufficiency of disclosure.

28.1 According to the Case Law of the Boards of Appeal, the patent, possibly complemented by common general knowledge, must provide the skilled person with the necessary information to carry out the invention over the whole scope claimed (see decisions in the Case Law of the Boards of Appeal of the EPO, 10th ed. 2022, II.C.5.4). However, the existence of a non-working embodiment does not necessarily lead to a finding of insufficient disclosure. As stated in decision T 292/85, "*An invention (here: biological) is sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention. Then the non-availability of some particular variants or unsuitability of some unspecified variants of a functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge which provide the same effect for the invention. The disclosure need not include specific instructions as to how all possible component variants within the functional definition should be obtained*" (see Headnote 1). This was confirmed in the decision of the Enlarged Board of Appeal G 1/03, which states "*If a claim comprises non-working embodiments, this may have different consequences, depending on the circumstances. Either there is a large number of conceivable alternatives and the specification contains sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with reasonable effort. If this is the case, the inclusion of non-working embodiments is of no harm*." (see point 2.5.2 of the Reasons). Thus, whether the existence of a non-working embodiment leads to a finding of insufficient disclosure is to be assessed on a case by case basis. For this assessment, the relevant

question in the present case is whether the information provided in the patent and the patent application as filed guides the skilled person to achieve the effects stated in the claim. To do this, it is first necessary to establish how the skilled person would interpret claim 1.

28.2 As set out in point 27. above, claim 1 does not combine a specific protein with protection against a specific serotype, much less in a specific amount of protein. Most importantly, however, the skilled person would not interpret the claim to mean that each of the four proteins listed can confer protection against every existing strain of *S. suis*, much less irrespective of the amount of protein used in the vaccine. In fact, the claim is limited to vaccine compositions comprising "*an effective amount*" of the protein. In the board's view, the technical effect defined in claim 1 is rather attaining homologous and heterologous protection with a vaccine composition comprising one of the proteins listed. Accordingly, what is required to meet the requirements of sufficiency of disclosure is that the patent provides guidance on how the invention can be carried out for each of the proteins, i.e. how protection against at least one or more serotypes can be achieved.

28.3 In the present case, it is part of common general knowledge that the amount of protein has an impact on the protection conferred by a vaccine. The skilled person would therefore test the amount accordingly. Moreover, the patent is not silent on the amount but gives not only examples (see example 2) but also a range for this amount, namely 50 to 2000 µg (see claim 4).

28.4 Therefore, the board concludes that the doses used in document D3 do not disprove the teaching in the patent, which is not limited to the lower end of the range in claim 4. The doses used in documents D13 and D14 are either identical or close to the amount used in example 2 of the patent and therefore confirm the teaching in the patent. The board concludes that, on the basis of the guidance in the patent, the lack of efficacy of the composition containing 50 µg of protein was no impediment to the skilled person carrying out the invention in respect of vaccines comprising a protein of the amino acid sequence SEQ ID NO: 2.

The experimental results in documents D14 and D15

29. Document D15 was put forward by the opponent to substantiate the serious doubts it raised. Document D14 is a patent application filed by the opponent which was considered under points 17. to 19. above. It is considered again here together with document D15 since both documents report studies on heterologous protection. In particular, both relate to experiments with a challenge strain belonging to serotype 9 ST16, like document D3, and unlike document D13 (ST94) and example 2 of the patent (ST99).

30. In the decision under appeal, the opposition division considered that document D15 also showed that a protein of the amino acid sequence of SEQ ID NO: 2 did not confer protection against infection by a strain of serotype 9, sequence type 16 (ST16). This is also an argument maintained by the opponent in the appeal proceedings.

31. Document D3 was considered in points 22. to 24. above. For the present purposes, the relevant difference

between documents D15 and D3 lies in the amount of protein used in the vaccine. Unlike document D3, document D15 concerns protein amounts identical to those used in example 2 of the patent - 250 µg . It describes testing of a vaccine composition containing a protein having the amino acid sequence SEQ ID NO: 2, used in a prime-boost protocol. The efficacy of the vaccine composition was evaluated *inter alia* by an average clinical score and by survival to challenge. The results were as follows: an average clinical score of 12 versus 19, and mortality rate of 3/12 versus 4/12, for vaccinated animals versus non-vaccinated (control) animals. This document concludes that the protein did not provide protection against the challenge strain, as there were no statistically significant differences between the vaccinated and control groups.

32. The parties were in dispute as to which conclusions could be drawn from this document.

33. The patent proprietor sought to challenge the conclusions in document D15 by arguing that differences between the vaccinated and control groups, such as an improvement in survival rates, may or may not be apparent depending on the size of these groups and on the mortality rate in the control group. The parties put forward several explanations for the low mortality rate observed in the control group in document D15 (4/12; see point 31. above) compared to that in document D14 (9/10; see point 19. above). However, such explanations do not need to be discussed further since they are immaterial to the patent proprietor's argument that a low mortality rate impacts the experiment's ability to show a statistically significant difference between the groups. Taking into account both the

results in document D14 (discussed above under points 22. to 24.), where indeed the mortality rate in the control group was much higher, and it was concluded that the protein provided protection against infection, and those in document D15, the board finds it convincing that the low mortality rate in document D15 is a valid explanation for the observed lack of statistically significant difference between the groups and thus for the discrepancy between the conclusions in these two documents. The opponent's line of argument pointing out that a skilled person assessing the efficacy of the vaccine would evaluate the other parameters in the study in addition to the mortality rate does not assist the opponent's case. According to the opponent the statistical analysis would be possible in case of 100% survival in the vaccinated group (see document D20). However, the basis for the board's assessment is the evidence in document D15. Therefore, the lack of statistical significance in document D15 cannot demonstrate the lack of protection and cannot substantiate reasonable doubt.

Document D23

34. This declaration was filed by the opponent after the communication of the board pursuant to Article 15(1) RPBA and its admittance into the appeal proceedings was contested. It relates to the antibody titres determined in document D3. However, the board did not have to decide on its admittance since its contents did not affect the conclusions drawn by the board from document D3, for the following reasons.

35. This declaration was filed in support of the argument that the observed lack of protection in document D3 was not due to poor antibody response to the vaccine, given

that the results showed seroconversion. Therefore heterologous protection would have been expected. However, the board already considered above the opponent's argument that heterologous protection would have been expected (see point 25.). The board held that the experiments in document D3 did not reproduce those in the patent and therefore could not call the latter into question. Moreover, the consequences of the results in this document for sufficiency of disclosure were assessed in light of the case law relating to "non-working embodiments" (see point 28.).

Conclusion

36. In light of the foregoing, the ground for opposition under Article 100(b) EPC does not prejudice maintenance of the patent as granted.

Inventive step (Articles 100(a) and 56 EPC)

The closest prior art

37. The parties were in disagreement as to whether document D5 or document D6 represented the closest prior art.

38. Document D5 concerns the efficacy of a bacterin vaccine based on *S. suis* serotype 2, and of a subunit vaccine based on a *S. suis* serotype 2 murein-associated protein fraction (MAP), for protection against infection with *S. suis* serotypes 2 and 9.

Document D6 concerns the identification in *S. suis* of the host-specific IgM protease designated IdeSsuis.

39. The opponent relied on document D6 as representing the closest prior art and selected the following passage of this document:

"*Identification of the protease cleaving IgM bound to the bacterial surface should help to improve vaccines against S. suis. Induction of opsonizing antibodies is crucial for the protective efficacy of an S. suis bacterin (27,45). As complement is important for the immunoglobulin-mediated killing elicited by an S. suis bacterin (unpublished results) and* Ide_{Ssuis} *promoted survival in blood of a vaccinated piglet, we hypothesize that neutralization of the* Ide_{Ssuis} *IgM protease activity might substantially improve the protective efficacy of bacterins or other future vaccines inducing opsonizing antibodies.*" (see page 939, right-hand column, third paragraph).

40. Claim 1 is directed to a vaccine composition for the therapeutic effect stated in the claim, which includes prophylaxis of *Streptococcus suis* infection. Therefore, the embodiment disclosed in document D6 that is of relevance for the assessment of inventive step must relate to a vaccine composition for the same therapeutic use. Document D6 concerns the function and properties of an IdeSsuis protein. The passage cited by the opponent addresses the possible applications of the findings relating to the IgM protease activity of IdeSsuis but does not disclose a vaccine composition with means of neutralising this activity. It likewise does not disclose any results on the protection conferred by any vaccine composition. The only vaccine composition identified in the passage quoted above is a generically mentioned bacterin vaccine. This corresponds to a composition containing killed whole bacteria of *S. suis* serotype 2 (see for example

page 932, left-hand column, first paragraph; see also document D5).

41. The difference between the vaccine for use of claim 1 and this prior art lies in the presence of the protein rIdeSsuis (SEQ ID NO: 2) or proteins of the amino acid sequence of SEQ ID NOs 1, 6 or 7, all sharing the domain Mac-1 present in rIdeSsuis.

The technical effect and objective technical problem

42. The patent does not include a comparison of the protection against serotype 9 *S. suis* infection conferred by a vaccine containing one of these proteins and a bacterin vaccine. However, according to document D5, a bacterin vaccine based on *S. suis* serotype 2 did not confer protection against serotype 9 *S. suis* infection (abstract). As regards the vaccine composition in claim 1, the board has, in the context of sufficiency of disclosure (see point 36. above), come to the conclusion that the patent discloses the suitability of a vaccine containing a protein of SEQ ID NO: 2 for protection against infection by serotype 9. It has not been contested that the proteins of the amino acid sequences SEQ ID NOs 1, 6 and 7 would also display this suitability. According to the patent, the domain Mac-1, which is shared by these proteins, is highly conserved between the serotypes, shows IgM protease activity and is responsible for their immunogenic activity (see paragraphs [0023] and [0040] of the patent). Furthermore, the technical effect of homologous protection was not in dispute.

43. In conclusion, the technical effect that may be attributed to the distinguishing feature is homologous and heterologous protection against *S. suis* infection.

Accordingly, the board sees the objective technical problem in the provision of a vaccine against *S. suis* infection which confers homologous and heterologous protection.

44. The opponent contested this technical effect, on the basis of the evidence brought forward in the context of sufficiency of disclosure. Heterologous protection was not achieved over all embodiments claimed and for that reason could not be taken into account when formulating the objective technical problem. According to the opponent, the board's conclusions in relation to sufficiency of disclosure did not apply here either. When assessing inventive step, it sufficed for the opponent to cast reasonable doubt as to whether the technical effect was achieved - reference was made to decision T 1797/09.

45. In point 28.2 above, the board set out how it construes claim 1. The claim construction applies here too. It was not in dispute that any failure of the vaccine composition to attain the therapeutic effects in the claim was to be considered under sufficiency of disclosure. Therefore, whether the vaccine compositions defined in claim 1 attained heterologous protection against *S. suis* infection, and more particularly infection caused by serotype 9, was assessed under sufficiency of disclosure. In the present case the evidence submitted by the opponent could not convince the board that the embodiment relating to protection against serotype 9 infection could not be carried out. In short, the board was not convinced by the evidence in the form of documents D3 and D15, in view of the evidence in the form of documents D13 and D14 and the evidence provided in the patent and patent application in example 2. It was concluded that they do attain the

therapeutic effect required by the claim (see point 36.).

46. Therefore, the opponent's argument, according to which there is a lower threshold for calling into question a technical effect in the context of inventive step than in the context of sufficiency of disclosure, plays no role here. This is the case because the board is convinced that the arguments and evidence brought forward by the opponent are not sufficient for calling the technical effect into question. Decision T 1797/09 cited by the opponent concerns the shift of the burden of proof in the context of determining the technical effect associated with a claimed feature. According to this decision "*...if the Opponent succeeds to cast reasonable doubt on the alleged effect, the burden to proof its allegations is shifted to the Patent Proprietor*" (Reasons 2.7). This, however, does not assist the opponent's case, since the board concluded that the credibility of the therapeutic effect provided in the patent is not put into question by the evidence submitted by the opponent. The board cannot derive from decision T 1797/09 any basis for re-evaluating the documents and arguments provided above in the context of sufficiency of disclosure.

Obviousness

47. The question to be addressed is whether the skilled person would have added IdeSsuis protein to the bacterin vaccine disclosed in document D6.

48. According to the opponent, the skilled person would have arrived at this solution based on document D6 alone. The board is not persuaded by this line of argument.

48.1 The passage cited by the opponent from page 939, addresses the IgM protease function of IdeSsuis. The sentence "*Ide_{Ssuis} promoted survival in blood of a vaccinated piglet*" relates to its role in *S. suis* evading the host's immune system. In view of this role, it is suggested that neutralising it might improve the efficacy of a vaccine. However, this is not followed by any statement or suggestion that it may be used to elicit protective antibodies or that its neutralisation means it can be used to elicit antibodies. The opponent's argument relies in particular on the following sentence: *"we hypothesize that neutralization of the Ide_{Ssuis} IgM protease activity might substantially improve the protective efficacy of bacterins or other future vaccines inducing opsonizing antibodies".* The opponent argued that this document addressed the problem, identified in document D5, of lack of opsonising antibodies, and read the term "neutralization" in this sentence to mean eliciting antibodies against IdeSsuis. However, the board does not agree that the document addresses such a problem, since it merely refers to opsonizing antibodies in the following context: "*Induction of opsonizing antibodies is crucial for the protective efficacy of an S. suis bacterin*" (see same passage). Moreover, like the rest of the document, this sentence is silent about the use of this protein as a vaccine against *S. suis* infection. There is also no mention of eliciting antibodies to IdeSsuis. In conclusion, in document D6 there is no suggestion of adding IdeSsuis protein to the bacterin vaccine or using it on its own as a vaccine.

48.2 The above notwithstanding, any mention of neutralising the protease activity of IdeSsuis is not linked to antibodies to *S. suis* serotype 9. Therefore, for this

reason too, the skilled person seeking to solve the above-formulated problem would not have found the claimed solution in this document. It is immaterial that figure 3 shows that IdeSsuis occurs in several serotypes of *S. suis* because this document does not identify the protein as an antigen for eliciting protective antibodies.

49. Document D10 would not have led the skilled person to the claimed solution either.

49.1 It has been argued that, since this document cites document D6, the skilled person would consult this document for a solution to the posed problem. This argument is not convincing, as the skilled person would start with the closest prior art - document D6, according to the opponent, not document D10.

49.2 Whether the skilled person would consult document D10 has to be assessed in light of the problem to be solved. Even if the problem were as formulated by the opponent, namely how to arrive in practice at the neutralisation of IdeSsuis IgM protease activity, there is no apparent reason to consult this document, as it does not concern *S. suis*, or its proteases or neutralisation of protease activity or bacterin vaccines.

49.3 This document concerns the protease IdeS from a different species, namely *Streptococcus pyogenes*. It mentions that protection against infection was observed with the protease of *S. pyogenes* and with a homologue from S. equi spp. (see section 1.4.11). The following section is dedicated to homologues and mentions the protease of *S. suis*. It is however highlighted that this differs from all other known homologues in that it

does not cleave IgG but rather IgM. Only its N-terminal sequence is homologous to IdeS and its approximately 700 C-terminal amino acids are not present in IdeS (see section 1.4.12). The board considers that, from this single mention of homology with the protease of *S. suis*, the skilled person cannot infer that this protease too would confer protection against infection. Indeed, the passage relating to the IdeS protein family and use thereof in vaccines (section 1.4.11) is not linked to that relating to the *S. suis* homologue. Moreover, the latter is specific to cleaving IgM of pig and wild boar and the identity between the amino acid sequences is low.

50. In light of the foregoing, the board concludes that the subject-matter of claim 1 is not obvious from document D6 taken alone or in combination with document D10. Thus, the ground for opposition under Article 100(a) EPC in combination with Article 56 EPC does not prejudice maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The appeal of the opponent is deemed not to be filed.

2. The decision under appeal is set aside.

3. The patent is maintained as granted.

4. The appeal fee paid by the opponent is reimbursed.

The Registrar: The Chairwoman:

A. Wille M. Pregetter

Decision electronically authenticated