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Datasheet for the decision of 29 February 2024

Case Number: T 2107/21 - 3.3.04

Application Number: 14808935.2

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Title of invention:
Swine vaccine against PRRS and Lawsonia intracellularis

Patent Proprietor:
Intervet International B.V.

Opponent:
Boehringer Ingelheim Vetmedica GmbH

Headword:
PRRS and Lawsonia combination vaccine/INTERVET

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

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Case Number: T 2107/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 29 February 2024

Appellant: (Opponent)	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Respondent: (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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 October 2021 rejecting the opposition filed against European patent No. 3 076 997 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	L. Bühler
Members:	B. Rutz
	S. Albrecht

Summary of Facts and Submissions

I. The appeal by the opponent (appellant) lies from the decision of the opposition division to reject the opposition against European patent No. 3 076 997 (patent), entitled "*Swine vaccine against PRRS and Lawsonia intracellularis*". The patent was granted with ten claims.

Claim 1 as granted reads as follows:

"1. A vaccine comprising in combination an adjuvant, a live attenuated PRRS virus and an inactivated *Lawsonia intracellularis* antigen, wherein the inactivated *Lawsonia intracellularis* antigen comprises killed whole cell *Lawsonia intracellularis* bacteria."

II. The opposition proceedings were based on the grounds of Article 100(a) EPC, on novelty (Article 54 EPC) and inventive step (Article 56 EPC), and Article 100(b) EPC.

III. The patent proprietor (respondent) replied to the appeal and re-filed the set of claims filed as an auxiliary request before the opposition division (auxiliary request).

IV. The board summoned the parties to oral proceedings, as requested, and informed them of its preliminary opinion in a communication under Article 15(1) RPBA 2020.

In this communication, the board indicated, *inter alia*, that it considered the subject-matter of claim 1 of the main request (i.e. patent as granted) to lack an

inventive step over the disclosure of document D10 in combination with the disclosure of document D5 or D6.

V. Oral proceedings took place before the board on 29 February 2024 in the presence of all parties. In the course of these proceedings, the respondent withdrew its auxiliary request.

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

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

D1	WHO Vaccine Safety Basics learning manual, 2013, 50-4
D5	WO 2009/127684
D6	WO 2009/144088
D8	WO 2006/099561
D10	R. Deitmer et al., "*Wirksamkeit und Sicherheit der teilweise zeitgleichen Verabreichung von vier Ferkelimpfstoffen in einem deutschen Betrieb*", Praktischer Tierarzt 90(4), 2009, 346-55
D11	Technical manual 3.0, 2006, 98 (http:/ www.thepigsite.com/publications/2/ileitis)
D13	WO 2007/116032

D14 WO 2013/152086

D15 R. Jones et al., "Controlling PCV2 and co-infections to reduce the impact of PCVAD in growing pigs", Allen D. Leman Swine Conference, 2007

D19 Product information on Ingelvac® PRRS MLV

D20 Product information on ReproCyc® PRRS-PLE

D24 Lecture by M. De Wilde, 2016

D32 M. B. Roof et al., "*LACK OF INTERFERENCE STUDIES TO EVALUATE A MODIFIED LIVE PORCINE REPRODUCTIVE AND VACCINE (INGELVAC® PRRS MLV) WHEN USED IN COMBINATION WITH A MYCOPLASMA HYOPNEUMONIAE-HAEMOPHILUS PARASUIS- ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN USING A HOST ANIMAL CHALLENGE MODEL*", The 16th International Pig Veterinary Society Congress, Melbourne, Australia, 17-20 Sept. 2000

D36 Product information on Porcilis® PRRS

D37 G. Labarque et al., "*Impact of genetic diversity of European-type porcine reproductive and respiratory syndrome virus strains on vaccine efficacy*", Vaccine 22, 2004, 4183-90

D48 MSDS of ReproCyc® PRRS PLE

VIII. The appellant's submissions relevant for the present decision are summarised as follows.

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

The subject-matter of claim 1 differed from the disclosure of document D10 in that:
- an adjuvant was used

- the *Lawsonia intracellularis* vaccine was inactivated *Lawsonia intracellularis* antigen comprising killed whole cell *Lawsonia intracellularis* bacteria

The fact that in D10 the *Lawsonia intracellularis* and PRRS virus antigens were not present in the same preparation did not distinguish this disclosure from the claimed subject-matter because, due to the definition of "combination" in paragraph [0004] of the patent, separate simultaneous administration was covered by the claim.

Killed whole cell *Lawsonia intracellularis* did not bring about any improvement on any health or performance parameter, and the addition of an adjuvant was merely a necessary consequence of replacing live with killed vaccine. The objective technical problem to be solved could only be seen in the provision of an alternative combination vaccine against PRRS virus and *Lawsonia intracellularis*.

Starting from document D10, the skilled person would derive that the described simultaneous administration of *Lawsonia intracellularis* and PRRS vaccines achieved improved performance parameters and at the same time provided a solution to the problem of facilitating different vaccinations during the short suckling period (D10, Summary). Given the technical problem posed, it would be the logical next step for the skilled person to provide these two vaccines as a true combination vaccine (i.e. both antigens in one preparation) to simplify the combined vaccination against *Lawsonia intracellularis* and PRRS virus.

The skilled person would seek options for administering PRRS and *Lawsonia intracellularis* antigens by the same

route. Accordingly, the skilled person would look for approaches where either *Lawsonia intracellularis* was administered intramuscularly or where PRRS virus was administered orally to arrive at a common administration mode. In this search, the skilled person would come across documents D5 and D6. These documents contained experimental data showing that *Lawsonia intracellularis* killed whole cell vaccine (bacterin) provided protection against infection when given to the animal via the intramuscular route with an adjuvant and in the form of a combination vaccine.

In view of this, the skilled person would have had a clear incentive to try to combine a live attenuated PRRS virus antigen, which was established for intramuscular administration, with killed whole cell *Lawsonia intracellularis* bacteria, which were taught in D5 and D6 as being combinable with other intramuscularly administered antigens (*M. hyopneumoniae* and PCV). From D5 and D6, the skilled person would also have derived in an obvious manner the formulation of the combination vaccine with an adjuvant.

Furthermore, in view of the above-summarised experimental data in D5 and D6, the skilled person would have had a reasonable expectation that a combination vaccine as defined in claim 1 would solve the technical problem posed. This understanding would have been fully in line with the skilled person's background art knowledge of previous reports on the successful use of live attenuated PRRS virus in combination with vaccines directed against other pathogens (as disclosed in D13 to D15 and, in particular, the marketed combination vaccine ReproCyc® PRRS-PLE (D20) comprising live attenuated PRRS virus and bacterins from *Leptospira spec.* and *Erysipelothrix*

rhusiopathiae). Therefore, there was no indication available before the priority date that live attenuated PRRS virus could lose efficacy when combined with an antigen from another pathogen. Thus, the subject-matter of claim 1 lacked inventive step in view of D10 and either D5 or D6.

IX. The respondent's submissions relevant for the present decision are summarised as follows.

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

Starting from D10, the difference with the current invention was three-fold:
1) the *Lawsonia* antigen being killed whole cell antigen
2) the combination of the two antigens in one formulation
3) the presence of an adjuvant

There was no prior art on file that pointed to these three features as a solution to arrive at a safe and efficacious combination vaccine. At best there were isolated references for each feature that a skilled person could have chosen, but no teaching that the combination of these features would lead to the claimed vaccine with a reasonable expectation of success.

Although the desire to devise combination vaccines was recognised in document D10, it used four vaccines as monovalent vaccines and administered them at two different times at different sites. If no interference for swine vaccines had been expected in general by a skilled person, the obvious solution would have been to combine the antigens in one vaccine formulation. However, document D10 avoided that and did not even suggest it. So document D10 as a starting point even

taught away from combining monovalent vaccines in one formulation. This made the jump to document D5 (or document D6) not obvious.

Even if the skilled person had contemplated document D5 when starting from document D10, they would have noticed that document D5 was explicitly concerned with a combination vaccine in which all antigens were non-live. This prerequisite could not be combined with the starting point of document D10, i.e. a live attenuated PRRS vaccine. So if the skilled person had wanted to combine the teachings of document D10 with those of document D5, against the implicit warning in document D10 not to put the different antigens in one preparation, the skilled person would at the same time have been prompted to use killed PRRS virus as the antigen, and thus would have ended up with a vaccine different from the one claimed.

The co-administration of antigens was not always successful, even when it was known that the two antigens had been successfully used as standalone antigens or in other combination vaccines before. The underlying phenomenon of interference was common knowledge and thus always in the back of the mind of the skilled person when contemplating a new combination of antigens. Interference had to be assessed on a case-by-case basis, thus adding a layer of unpredictability. Evidence for this could be found in documents D1 (see page 50) and document D24 (see slide 9). There was no proof on file that the skilled person would not have expected such interference for *Lawsonia* and PRRS antigens (see documents D8, D10, D13 and D32).

The unpredictability of interference (as shown in the current patent) corresponded to the unpredictability of

synergism between compounds in any constitution. Under the established case law of the boards, if an unpredictable effect occurred, it typically lead to recognition of an inventive step.

X. The appellant requested that the decision under appeal be set aside and the patent be revoked.

XI. The respondent requested that the appeal be dismissed and the patent be maintained as granted.

Reasons for the Decision

Claim construction - claim 1

1. The board understands a "vaccine comprising in combination an adjuvant, a live attenuated PRRS virus and an inactivated *Lawsonia intracellularis* antigen" to comprise all three listed components. The claimed vaccine also relates to kits of parts or separate compounds which can be administered independently of each other as long as "*the antigens are provided in combined form*" including "*only after administration to the subject animal*" (see paragraph [0004] of the patent). The claim does not prescribe whether the vaccine is a mix provided by the manufacturer, mixed on site before administration, mixed in a device before being injected or combined in the subject animal after injection. The skilled person would understand that the latter requires administering the two antigens at roughly the same time and site to allow the antigens to combine (see paragraph [0004] of the patent: "*for example by injection of two separate vaccines at the same injection site*"). Vaccines administered at two distant sites in the animal or via two different routes (e.g. oral and intramuscular) are not part of the

claimed subject-matter. This interpretation was not contested by the respondent.

Inventive step (Article 100(a) and Article 56 EPC)
Document D10

2. Document D10 represents a suitable starting point for an inventive-step analysis. It discloses the administration of a PRRS live attenuated vaccine and a *Lawsonia intracellularis* live attenuated vaccine on the same day but through different routes (see page 350, left-hand column, lines 5 to 9). The *Lawsonia intracellularis* live attenuated vaccine Enterisol® Ilietis used in document D10 is administered orally (see document D11), while the live attenuated Ingelvac PRRS® MLV is injected intramuscularly (see document D19). Document D10 reports no adverse reactions and an improvement in all assessed performance parameters (see page 351, left-hand column, bottom paragraph), i.e. it reports a safe and efficacious vaccination against the two diseases.

Differences, effect(s), objective technical problem and solution

3. In line with the board's claim construction (see point1. above), the differences of the subject-matter claimed compared to the disclosure of document D10 are that:
   - the components are in a form which allows for their administration concomitantly via the same route and at the same site
   - the vaccine comprises killed whole cell *Lawsonia intracellularis* bacteria (bacterin)
   - the vaccine comprises an adjuvant

4. The patent contains no comparative data to show an improvement over the vaccination disclosed in document D10, and the respondent has not argued that there was any improvement. The only effect that can be associated with the above differences is therefore an easier and more economic handling of the vaccination which is also less stressful for the animals.

5. The objective technical problem vis à vis the disclosure of document D10 can be formulated as the provision of an alternative combined vaccination against PRRS and *Lawsonia intracellularis* infections allowing for an easier and more economic handling of the vaccination which is less stressful for the animals.

6. The fact that the claimed vaccine was "safe and efficacious", as argued by the respondent, does not, however, form part of the objective technical problem because even if the data provided in the patent were considered to render a safe and efficacious vaccine credible, this does not constitute a difference compared to the vaccination disclosed in document D10.

7. As a solution to this problem, a vaccine in accordance with claim 1 is provided.

Obviousness

8. Document D10 (page 348, right-hand column, first full paragraph) notes: "*For veterinary medicine, Olbertz (1990) stated that economic vaccine application can be achieved by combining vaccines. For reasons of cost and labour savings and also to reduce physical and psychological stressors for the animal during the vaccination act, Olbertz already considered it*

desirable in 1990 to administer several vaccines at the same time or as a combination vaccine. Combination vaccines allow a considerable reduction in the number of injections required to build up immunity against different pathogens." (Translation by the board.) The skilled person thus learned from document D10 that concomitant administration of several vaccines as well as combination vaccines were advantageous and that the latter was desirable.

9. The respondent referred to the following passage on the same page in document D10 as an indication that the skilled person would, however, be cautious to combine mono-vaccines: "*Although there is intensive research on the development of innovative new products, very few combination vaccines for pigs are currently authorised in Europe due to the strict authorisation requirements.*" (Translation by the board.)

10. The board, however, does not agree that the latter statement in document D10 would indicate to the skilled person that particular hurdles or difficulties were to be expected when combining known mono-vaccines. The skilled person in the case in hand is not a veterinarian or a swine producer but a researcher involved in the development and testing of swine vaccines in a pharmaceutical company or academic setting. This skilled person is therefore not limited to the vaccines approved and available on the market but has access to experimental vaccines disclosed in scientific articles or patent applications and can use known vaccines in new (and not yet approved) combinations. The fact that only a few combination vaccines had been approved at the time of publication of document D10, which is more than four years before the priority date, and the "*strict authorisation*

requirements" mentioned in document D10 are, in any case, not an impediment to trying out promising new vaccine combinations. Moreover, document D10 (page 348, right-hand column, first full paragraph) states: "*Particularly when vaccinating piglets, many veterinarians in the care of livestock are therefore faced with the question of simultaneous administration of vaccines that are authorised as mono-vaccines*" (translation by the board).

11. Document D10 (page 353, left-hand column, lines 8 to 12) also refers to already approved combination vaccines: "*In principle, pigs can be successfully vaccinated against different pathogens at the same time. In Germany, various vaccines are authorised for pigs that contain up to seven antigens or protect the pigs against up to two diseases.*" (Translation by the board.) This further indicates that the authors of document D10 considered not only simultaneous administration but also "true" combination vaccines to be promising, useful and economically advantageous.

12. Starting from document D10, the skilled person would thus seek a common administration route for both vaccines, implying either the oral or intramuscular route. In the absence of an improved effect, both alternatives would be equally obvious solutions to the problem.

13. Alternative *Lawsonia intracellularis* vaccines were known from documents D5 and D6. These vaccines comprise killed whole cell *Lawsonia intracellularis* and an adjuvant (Diluvac® Forte, see document D5, Example 2, page 10, lines 21 to 28). The experiments in document D5 show that the intramuscular administration of this vaccine resulted in a good immune response and

comparable or even better protection compared to the established live attenuated *Lawsonia intracellularis* vaccine Enterisol® Ilietis (see Tables 1 to 3 on pages 12 and 13, compare group 2, killed whole cell *Lawsonia intracellularis*, with group 1, live attenuated *Lawsonia intracellularis*).

14. The skilled person equally knew as part of their common general knowledge that the commercially available live attenuated PRRS vaccine, PRRS Porcilis®, contained the adjuvant Diluvac® Forte (see document D36, page 1 and document D37, page 4184, right-hand column, point 2.1).

15. Three partially interlinked questions remain.

1) Would the skilled person have combined a live attenuated PRRS and a killed whole cell *Lawsonia intracellularis*?

2) Would the skilled person have considered the combined administration of the two vaccines, for example by administering them at the same time into the same injection site?

3) Would the skilled person have had a reasonable expectation of success to obtain a safe and efficacious vaccination when administering the two vaccines in this way?

16. For the first and second questions, the appellant referred to a number of documents which show that live attenuated PRRS vaccines in combination with a variety of killed whole cell bacteria (bacterins) maintain safety and efficacy without interference or adverse reactions (see document D13, page 9, Example 1, Porcilis® PRRS with *M. hyopneumoniae bacterin*; document D14, pages 50 and 51, Examples 13 and 14, genetically modified PRRS virus (PRRS MLV) with PCV2 killed virus and *M. hyo* bacterial extract; document D32, Ingelvac®

PRRS MLV with *M. hyopneumoniae, H. parasuis, E. rhusiopathiae* bacterin; and documents D20 and D48, ReproCyc® PRRS-PLE, PRRS modified live virus with inactivated Parvo® (killed parvovirus), five *Leptospira* species and *Erysipelothrix rhusiopathiae* bacterin). The appellant further referred to documents showing that *Lawsonia intracellularis* bacterin could be successfully combined with other vaccines (see documents D5 and D6 for combinations with *M. hyopneumoniae* and PCV2 vaccines). Document D5 concludes: "*a combination vaccine comprising non-live Lawsonia intracellularis antigens in combination with Mhyo and PCV antigens is suitable to combat Lawsonia intracellularis as well as Mycoplasma hyopneumoniae and Porcine circo virus*" (page 18, lines 4 to 6).

17. In contrast, the respondent has not provided any indication in the prior art that would have led the skilled person to assume that the combination of live attenuated PRRS virus with killed whole cell *Lawsonia intracellularis* resulted in interference. For combined vaccinations, interference is commonly referred to as the interaction of antigens of the different vaccines to result in reduced efficacy of either one or both of the vaccines (immune interference), a reversion of toxicity, or a reaction with other vaccine components (see e.g. document D1, bottom of page 50). The respondent referred to the generally cautious approach of the skilled person when combining vaccines. The respondent referred to document D24, which summarises challenges for human combination vaccines. This document, however, is not prior art (see date on page 1: "*March 16, 2016*") and therefore cannot establish the mindset of the skilled person at the priority date.

18. The board, however, notes that there is nothing on file which could support immune interference from "incompatible" antigens. Even in document D24, the term appears without further definition or discussion. In the absence of convincing evidence and in view of the explanation that the immune system is normally able to respond to many antigens at the same time (see document D1, page 50, "Key point"), the respondent has failed to establish that such a general concern was part of the skilled person's mindset.

19. As regards possible incompatibilities between the antigens and other vaccine components, e.g. adjuvants, a concern can be acknowledged in view of document D1. However, such a concern is not a prejudice. Moreover, in the current case, the adjuvant in question, Diluvac® Forte, was used for both components, as noted by the appellant.

20. The respondent further referred to document D1, a "*Vaccine Safety Basics learning manual*" from the World Health Organization, which states on page 50: "*It is very important, however, that combination vaccines are carefully tested before introduction. For instance, adjuvants in a combination vaccine could reduce the activity of one antigen and excessively increase the reactivity of another antigen. There could also be interactions with other vaccine components such as buffers, stabilizers and preservatives. With all combinations, manufacturers must therefore evaluate the potency of each antigenic component, the effectiveness of the vaccine components when combined to induce immunity, risk of possible reversion to toxicity, and reaction with other vaccine components.*"

21. The board does not consider such general requirements for achieving market authorisation an indication that combination vaccines are fraught with major difficulties and uncertainties. Moreover, document D1 itself (on the same page under "*Key point*") notes: "*No evidence exists that the administration of several antigens in combined vaccines overwhelms the immune system, which has the capability of responding to many millions of antigens at a time. Combining antigens usually does not increase the risk of adverse reactions. In fact, it can lead to an overall reduction in adverse reactions.*"

22. The respondent also argued that the occurrence of interference for combination vaccines was unpredictable in a similar way as was a synergistic effect for compositions comprising several active compounds. The absence of interference was therefore an indicator for the presence of an inventive step. The board does not agree with this analogy. Immune interference for combination vaccines, albeit a relevant concern, remains the exception (see e.g. the statement in document D1, cited above), and there is no specific indication on file in that regard (see point 18. above). To the contrary, all combination vaccines referred to by the parties which comprise either PRRS live attenuated virus or *Lawsonia* bacterin showed no interference effects. Moreover, the same adjuvant (Diluvac® Forte) had been successfully used with both vaccine components, so no incompatibilities or cross-reactions were to be expected.

23. The board therefore concludes that the skilled person seeking alternative vaccines for protecting swine from *Lawsonia intracellularis* and PRRS infections would have turned to the killed whole cell *Lawsonia*

intracellularis vaccine disclosed in document D5 and would have realised that one adjuvant used with this vaccine, Diluvac® Forte (see page 10, lines 21 to 28), is compatible with a live attenuated PRRS virus vaccine (as evidenced by commercially available Porcilis® PRRS, which is dissolved in Diluvac® Forte, see document D36).

24. Both vaccines are to be administered intramuscularly. In view of the many reports of pre-mixed combination vaccines of live attenuated PRRS virus with different bacterins (killed whole cell bacteria, see point 16. above), the skilled person would have had no reason to choose the more complicated way of injecting the two vaccines separately and independently into different sites but would have injected them into the same site, preferentially by mixing before the injection.

25. Therefore, only the third question remains, i.e. whether the skilled person had a reasonable expectation of success to obtain a safe and efficacious vaccine when combining the live attenuated PRRS vaccine used in document D10 with a killed whole cell *Lawsonia intracellularis* bacterin and the corresponding adjuvant, Diluvac® Forte, both disclosed in document D5.

26. The appellant pointed to the relevant prior art that the skilled person was aware of:

- document D10 showing that simultaneous vaccination via different administration routes of a live attenuated PRRS virus and a live attenuated *Lawsonia intracellularis* is safe and efficacious
- several documents showing that live attenuated PRRS virus combined with bacterins from different

pathogenic bacteria is safe and efficacious (see point 16. above)

- documents D5 and D6 showing that combination vaccines of killed whole cell *Lawsonia intracellularis* with recombinant PCV2 antigen and inactivated *M. hyopneumoniae* are safe and efficacious

From this evidence, the skilled person had every reason to expect a safe and efficacious vaccine when mixing or administering to the same site the two known vaccines.

27. The respondent, in contrast, argued that the skilled person reading document D10 would instead combine the non-live vaccines disclosed in D10, i.e. inactivated *M. hyopneumoniae* and recombinant PCV2 antigen, with a killed whole cell Lawsonia vaccine because it was preferable not to combine live and non-live vaccines. This was also apparent from documents D5 and D6, in which only non-live vaccines were combined with the *Lawsonia* bacterin. The respondent also referred to the passage bridging pages 3 and 4 of document D5 which indicate that "*combination of live antigens however is not straightforward given the high chance of interference between the antigens and the difficulty of manufacturing such a live combination vaccine*".

28. The board does not agree with this argument because there is no evidence on file that live and non-live vaccines cannot be mixed. In contrast, the appellant has cited a number of documents in which a live attenuated PRRS vaccine is mixed with non-live bacterins. The passage on pages 3 and 4 of document D5 refers to the mixing of several live vaccines which can be problematic, but this does not apply to the claimed vaccine. The board can therefore see no preference of the skilled person to mix only non-live vaccines.

29. Furthermore, the respondent has not provided evidence why the skilled person would be dissuaded from replacing the live attenuated *Lawsonia intracellularis* in document D10 with a killed whole cell *Lawsonia intracellularis* and the corresponding adjuvant, Diluvac® Forte, as disclosed in document D5, but relies on the assumption of a general cautious approach of the skilled person when combining vaccines.

30. Such general safety and efficacy concerns are not sufficient to put in doubt the reasonable expectation of success that the skilled person had in view of the many reports of successful combination vaccines involving either of the two active components in the claimed vaccine combination: i.e. live attenuated PRRS virus and killed whole cell *Lawsonia intracellularis.*

31. The subject-matter of claim 1 lacks an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision is set aside.

2. The patent is revoked.

The Registrar: The Chair:

I. Aperribay L. Bühler

Decision electronically authenticated