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Datasheet for the decision of 25 June 2015

Case Number: T 2597/11 - 3.3.07

Application Number: 03782368.9

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Language of the proceedings: EN

Title of invention:
MASTITIS TREATMENT WITH A COMBINATION OF PREDNISOLON AND CEPHALOSPORIN

Patent Proprietor:
Intervet International BV

Opponent:
VIRBAC S.A.

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4), 13

Keyword:
Late-filed evidence - admitted (yes)
Inventive step - technical prejudice in the art (no)
Late-filed request - justification for late filing (no)

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Case Number: T 2597/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 25 June 2015

Appellant: (Patent Proprietor)	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer (NL)
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Representative:	Macquet, Christophe Macquet & Associés Arche des Dolines 7, rue Soutrane 06560 Sophia Antipolis (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 October 2011 revoking European patent No. 1585497 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Boulois
Members:	D. Semino
	D. T. Keeling

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 22 September 2011 to revoke European Patent 1 585 497. The patent was granted on the basis of 10 claims, claims 1 reading as follows:

"1. A pharmaceutical composition for intramammary administration to a non-human mammal, comprising a cephalosporin, prednisolone and a pharmaceutically acceptable carrier, **characterised in that** the composition comprises at least 20 mg of prednisolone / unit dose."

II. The decision was based on the patent as granted and on two sets of claims filed as auxiliary requests 1 and 2 during the oral proceedings before the opposition division on 22 September 2011.

Claim 1 of auxiliary request 1 included with respect to granted claim 1 the specification that "the pharmaceutically acceptable carrier comprises an oily base". In addition to that, claim 1 of auxiliary request 2 limited the quantity of prednisolone / unit dose to precisely 20 mg.

III. In the decision the following documents were cited inter alia:

D2: Lohuis J.A.C.M. et al. "Effect of Steroidal Anti-Inflammatory Drugs on *Escherichia coli* Endotoxin-Induced Mastitis in Cows", Journal of Dairy Science, volume 72, 1989, pages 241 -249

D6: Matsuda K., Journal of Veterinary Medicine, volume 48(12), 1995, pages 985-988 (a first translation was filed by the patent proprietor with letter of 26 July 2011 and a second translation was filed by the opponent with letter of 2 September 2011)
D7: "Le manuel vétérinaire Merck (Deuxième édition française)", Editions d'Après, Paris, 2002, pages 1824-1829
D12: "Prednisolone (as free alcohol) Summary Report", The European Agency for the Evaluation of Medicinal Products, 1999, pages 1/7-7/7
D13: "Résumé des caractéristiques du produit: Cobactan LC pommade intramammaire", 23 November 2010, retrieved from the Internet on 21 September 2011

IV. The decision under appeal, as far as relevant to the present decision, can be summarised as follows:

a) Out of the many documents proposed by the parties D12 represented the closest prior art, as it was directed to the same purpose and required the minimum of modifications to arrive at the claimed subject-matter. The subject-matter of claim 1 of the main request differed from the disclosure in D12 in the nature of the used antibiotic and in the dose of prednisolone. There was no technical effect resulting from the first difference, whereas the dose of prednisolone appeared to improve the anti-inflammatory activity, so that the technical problem was the provision of an improved mastitis treatment. Even if documents D7 and D2 were concerned with possible adverse effects of higher prednisolone doses, they could not be considered to constitute a prejudice. As nothing could be identified in the prior art that would prevent the skilled person from increasing

the prednisolone dose when looking for an improved treatment, inventive step was lacking.

b) With regard to document D13, which was filed by the opponent for lack of inventive step of auxiliary request 1 with reference to the carrier comprising an oily base, it was found that, as the oily base carrier was one of the preferred embodiments, the document could have been filed earlier. Moreover, it could not be proven that the content of the document was the same at the priority date of the patent. On that basis D13 was regarded as late filed and was not admitted into the proceedings. The subject-matter of auxiliary request 1 differed from the disclosure of D12 in a further feature, namely the use of an oily base, which had no established additional effect. The same technical problem as formulated for the main request was therefore solved and the same conclusion of lack of inventive step was reached, as the use of an oily base was considered to be a common practice and therefore an obvious measure.

c) As to auxiliary request 2, it was considered that limiting the dose of prednisolone to exactly 20 mg/unit dose did not *prima facie* overcome the objection of lack of inventive step and consequently the request was not admitted into the proceedings.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant filed 24 sets of claims as auxiliary requests 1 to 24.

Claim 1 according to auxiliary request 1 corresponded to granted claim 1 with the specification that "the composition comprises prednisolone in an amount of 20 to 40 mg / unit dose". In claim 1 according to auxiliary request 4 the range was further limited to "20 to 30 mg / unit dose". Claim 1 according to auxiliary requests 7 and 10 corresponded to claim 1 according to auxiliary requests 1 and 4 respectively with the addition that "the pharmaceutically acceptable carrier is an oily base". Claim 1 according to auxiliary requests 13, 16, 19 and 22 corresponded to claim 1 according to auxiliary requests 1, 4, 7, 10 with the amendment of the antibiotic from "cephalosporin" to "cephapirin". Claim 1 according to the further auxiliary requests (2, 3, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 20, 21, 23 and 24) was identical to claim 1 according to one of the previous requests (to auxiliary request 1 for auxiliary requests 2 and 3, to auxiliary request 4 for auxiliary requests 5 and 6, to auxiliary request 7 for auxiliary requests 8 and 9, to auxiliary request 10 for auxiliary requests 11 and 12, to auxiliary request 13 for auxiliary requests 14 and 15, to auxiliary request 16 for auxiliary requests 17 and 18, to auxiliary request 19 for auxiliary requests 20, 21, 23 and 24).

With the statement setting out the grounds of appeal the appellant submitted additionally the following pieces of evidence:

D14: "The Merck Veterinary Manual, 8th edition", Merck & Co. Inc., 1998, pages 1824-1829
D15: Teale A.J. "Corticosteroids", in Bogan J.A. et al. "Pharmacological basis of large animal medicine", Oxford: Blackwell Scientific Publications, 1983, pages 428-451

D16: Roth J.A. et al. "Effect of Glucocorticoids on the bovine immune system", JAVMA, volume 180(8), 1982, pages 894-901
D17: Roth J.A. et al. "Effects of In Vivo Dexamethasone Administration on In Vitro Bovine Polymorphonuclear Leukocyte Function", Infection and Immunity, volume 33(2), 1981, pages 434-441
D18: Wesley I. V. et al. "Effects of dexamethasone on shedding of *Listeria monocytogenes* in dairy cattle", Am. J. Vet. Res., volume 50(12), 1989, pages 2009-2013
D19: Burton J.L. et al. "Regulation of L-selection and CD18 on bovine neutrophils by glucocorticoids: effects of cortisol and dexamethasone" Journal of Leukocyte Biology, volume 57, 1995, pages 317-325
D20: Swarbrick O. "Intramammary Treatment of Bovine Mastitis", The Veterinary Record, 1968, pages 2-6

VI. In the reply to the statement setting out the grounds of appeal the opponent (respondent) contested the non-admittance on document D13 into the proceedings, requested that documents D14 to D20 not be admitted and took position on the patent as granted as well as on all auxiliary requests.

VII. Oral proceedings were held on 25 June 2015. During the oral proceedings the respondent requested for the first time that auxiliary requests 1 to 24 not be admitted into the proceedings and the appellant withdrew auxiliary requests 12 and 21.

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

Admittance of documents

a) Documents D14 to D20 were filed with the statement of grounds as a reaction to the appealed decision. They had no particular complexity and made stronger a point already raised and crucial to the decision, namely the impact on the immune system of a high dosage of prednisolone. On that basis they should be admitted into the proceedings.

Main request - inventive step

b) The composition of granted claim 1 differed from the one of document D12, taken as the closest prior art, in the choice of a specific antibiotic and in the increased unit dose of prednisolone. The problem solved was the provision of a composition with improved anti-inflammatory activity while not compromising the antibacterial effect. The examples in the patent, in particular examples 4 and 5 in the patent showed that the problem was solved. The proposed solution, in particular the increase in the unit dose to at least 20 mg, was not obvious, as it was known that a high dosage of prednisolone would have a strong impact on the immune system, thereby impairing the antibacterial effect. This was shown in particular by the specialised manual D14, where seven warnings were given on the immunosuppressive effect of steroids, five of which were stated after the nuance was given in the document that historically some side effects of steroids had been overstated. Also document D15 to D20 confirmed the immunosuppressive effect and warned against high dosages. There was moreover no item of prior art which suggested the claimed

combination; in particular neither of documents D2 and D6 suggested the use of a dose higher than 20 mg. In D2 a 40 mg dose was tested, but there was no comparison with a lower dose and the high dose had a clear immunosuppressive effect. The teaching of D6 was not straightforward and there were contradictions between the different, equally valid translations; in particular it was not clear that a 30 mg dose was applied intramammary. On that basis the skilled person would not consider increasing the dose in order to solve the posed problem, so that the claimed composition involved an inventive step.

Request not to admit auxiliary requests 1 to 24

c) The auxiliary requests were systematic and structured, represented the last chance to defend the patent and had been on file since the beginning of the appeal proceedings. It was therefore not reasonable to request not to admit them only at the oral proceedings, nor to decide not to admit them.

Auxiliary requests - inventive step

d) The limitation to 20 to 40 mg prednisolone / unit dose corresponded to the highest efficacy shown by the examples. It was even most preferred to use 20 to 30 mg prednisolone / unit dose in order to obtain the desired effect with the smallest possible quantity. An oily base made the combination effective and not highly aggressive, so as to avoid immunosuppression. Cephapirin was a first generation cephalosporin which was advantageous, as it was active against gram

positive bacteria and was amongst the antibiotics not banned for animals. The introduction of one or more of these preferred features was a deliberate selection intended to limit the invention to the most preferred and the most advantageous embodiments. For these reasons the compositions according to the auxiliary requests involved the required inventive step.

IX. The arguments of the respondent, as far as relevant to the present decision, can be summarised as follows:

Admittance of documents

a) Document D13, which was not admitted by the opposition division, related to a commercial product available before the priority date (reference was made to the date of the first marketing authorisation) and showed that the use of an oily base for an intramammary composition was part of the common general knowledge. It should therefore be admitted into the proceedings. Documents D14 to D20, filed by the appellant, were not particularly pertinent. In particular D14 was simply the English version of D7 and the further documents did not relate to the specific drug, the specific antibiotics and intramammary administration and referred to higher dosages than those in the claims. On that basis they should not be admitted into the proceedings.

Main request - inventive step

b) The composition of claim 1 of the main request differed from the one of document D12, which was the closest prior art, in the different dose of

prednisolone and in the specification of cephalosporin as the antibiotic of use. While no effect could be acknowledged for the choice of cephalosporin, which was a well known antibiotic, a higher dose of prednisolone achieved a higher anti-inflammatory activity. The problem was the provision of a composition with improved anti-inflammatory activity. The increase of the prednisolone dose was an obvious solution to the problem in view of its known anti-inflammatory effect and of the disclosure of documents D6 and D2 which employed doses of 30 and 40 mg respectively. As to D6 the certified translation provided by the respondent made its teaching fully clear. Documents D14 to D20 did not support the presence of a prejudice, which could discourage the skilled person from increasing the dose. In particular D14 stated clearly that side effects of steroids had been overestimated in the past and pointed to the commonly known administration of steroids in combination with antibacterial agents. While at very high dosages immunosuppression could take place, there was nowhere an indication that it was the case for prednisolone at doses in the claimed range.

Request not to admit auxiliary requests 1 to 24

c) The auxiliary requests were in a large number and were not convergent. In view of that they should not be admitted. While it was the intention of the respondent to request not to admit the auxiliary requests since the beginning of the appeal proceedings, it was done only at the oral proceedings, as the responded waited to see which were the final requests of the appellant.

Auxiliary requests - inventive step

d) As the prior art contemplated increasing the dosage of prednisolone, it did not make any difference whether the claim included a unit dose of at least 20 mg, 20 to 40 mg or 20 to 30 mg, which amounted to arbitrary selections. There was no proven effect of the use of an oily base, which was a well known option for intramammary compositions. Also with respect to cephapirin there was no proven effect and all possible advantages mentioned by the appellant were known and not related to the specific formulation. On that basis the compositions according to all auxiliary requests did not involve an inventive step for the same reasons as outlined for the main request.

X. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or on the basis of the claims of one of the auxiliary requests 1 to 11, 13 to 20 and 22 to 24 as filed with the grounds of appeal.

XI. The respondent requested that the appeal be dismissed, that the auxiliary requests not be admitted into the proceedings, and that documents D14 to D20 not be admitted into the proceedings.

Reasons for the Decision

Admittance of documents D13 to D20

1. Document D13 was not admitted into the opposition proceedings on the basis that it was relevant for a

feature relating to one of the preferred embodiments (the carrier "comprises an oily base"), so that it could have been filed earlier, and that it could not be proven that its content was the same at the priority date.

1.1 While the Board sees no reason to doubt that the opposition division exercised its discretion using the correct criteria, the discretion of the Board can be exercised independently, in accordance with Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA).

1.2 In the present case, while D13 was submitted during opposition proceedings at the oral proceedings before the opposition division, in appeal proceedings the document has been discussed directly with the reply to the statement of grounds and its admittance has not been objected to by the appellant. Moreover, reference was made to new requests filed in appeal with the statement of grounds in which the relevant feature has been reformulated (the carrier "is an oily base") and combined with other features. Finally, reasons were given to support the availability of the product described in D13 before the priority date.

1.3 On that basis the Board finds it appropriate to admit document D13 into the proceedings.

1.4 Documents D14 to D20 were filed by the appellant with the statement of grounds to counter the reasoning on inventive step in the appealed decision, in particular with reference to the crucial point that there was no prejudice against increasing the dose of prednisolone. These documents were therefore timely filed by the appellant in appeal, they deal with one of the most

relevant points in the appealed decision and can be seen as a legitimate reaction thereto, so that the Board sees no reason under Article 12(4) RPBA not to admit them. On that basis documents D14 to D20 are admitted into the proceedings.

Main request - inventive step

2. Both parties agree with the appealed decision, as far as the choice of the closest prior art (document D12) and the identification of the distinguishing features (the choice of cephalosporin as the antibiotic of use and the increased unit dose of prednisolone, which is 10 mg in D12 and at least 20 mg in granted claim 1) are concerned. The Board has no reason to take a different approach.

2.1 Indeed D12 discloses the use of prednisolone as an ingredient in antibiotic preparations, which are indicated for intramammary administration for the treatment of bovine mastitis, with a usual dose of 10 mg prednisolone per infected quarter (D12, page 1/7, point 1, first paragraph).

2.2 In D12 no specific compound is disclosed with regard to the antibiotic and no dose different from the usual one of 10 mg prednisolone is mentioned.

3. As to the problem solved, while no submission was made with respect to an effect related to the choice of a specific antibiotic, there was disagreement between the parties as to whether maintenance of the antibacterial effect was to be included in the formulation of the problem solved via an increase of the prednisolone dose.

3.1 Example 2 in the patent (paragraphs [0041] to [0045]) shows the effect of different doses of prednisolone on local inflammation. Doses of 0 mg, 10 mg, 20 mg and 40 mg per injector together with 200 mg of cephapirin solution are tested (paragraph [0042]). As expected, the results in figure 1 show a dose related effect, i.e. higher dosages of prednisolone result in less severe signs of local inflammation. The improvement in anti-inflammatory activity, which is in itself credible as it is related to the expected function of the steroid, is therefore proven.

3.2 Examples 3 and 4 in the patent (paragraphs [0046] to [0054]) compare the effect of a composition containing only cephapirin and of one with cephapirin and 20 mg prednisolone with respect to the case of a non-treated control. As different doses of prednisolone are not compared, the examples are not suitable to provide any evidence on the effects of the claimed composition with respect to that of document D12.

3.3 Example 5 in the patent (paragraphs [0055] to [0059]) compares the efficacy of a composition with 20 mg prednisolone and an antibacterial compound (300 mg cephapirin) with the efficacy of a composition with 10 mg prednisolone and an antibacterial compound (200 mg amoxicillin combined with 50 mg clavulanic acid). The results in table 3 and figure 6 show that the higher dosage of prednisolone does not negatively influence the bacteriological cure rate. While the example is able to show that a satisfactory bacteriological cure rate is obtained with a dose of prednisolone at 20 mg, the fact that also the antibiotic is different in the two compositions does not make possible a direct comparison between different doses of prednisolone which could support the conclusion that the

antibacterial effect is maintained exactly at the same level.

3.4 The problem which can be considered as solved on the basis of the available evidence is therefore the provision of a composition with improved anti-inflammatory activity while the antibacterial effect is satisfactorily maintained.

4. It remains to be analysed whether the proposed solution, namely an increase in the dose of prednisolone while choosing a cephalosporin as antibiotic, is obvious in view of the available prior art.

4.1 The choice of a cephalosporin as antibiotic is nothing more than an arbitrary choice out of several equivalent alternatives, as acknowledged by the appellant, who did not defend the presence of an inventive step related to that choice.

4.2 As to the dose of prednisolone, an increase in the dose of the ingredient responsible for the effect it is desired to potentiate (the anti-inflammatory activity) is in itself an obvious measure, independently of the presence of a specific indication in prior art documents. In addition, documents D2 and D6 disclose doses in the claimed range for mastitis treatment by intramammary administration, thereby showing that such doses are contemplated by the skilled person. Document D2 is a study on the effects of steroidal anti-inflammatory drugs on Escherichia coli endotoxin-induced mastitis in the cow and discloses a dose of 40 mg prednisolone for intramammary infusion (see abstract, first sentence; table 1). The observation that some immuno-suppression takes place (page 243,

last but one paragraph; figure 3) does not change the fact that 40 mg is the dosage chosen for intramammary administration. In D6 the intramammary infusion administered to the treated cows suffering from mastitis contains 30 mg prednisolone (point 2.3 "Drugs employed and methods of administration", last sentence of the first paragraph in the translation of the patent proprietor and point 2.3 "Drugs used and administration method", last sentence of the first paragraph in the translation of the respondent, both translations conveying the same information).

4.3 While in view of that the increase in the dose of prednisolone to values within the range of claim 1 of the main request results in an obvious measure in order to solve the posed problem, the presence of an inventive step could in principle be acknowledged in the presence of a clear prejudice in the art, which would discourage the skilled person from performing that measure in view of the need to maintain a satisfactory antibacterial effect.

4.4 Document D14, which is the basic document used by the appellant to support the presence of such a prejudice, is a well-known veterinary manual, including a chapter on steroids in the section devoted to anti-inflammatory agents. In that chapter the immunosuppressive action of steroids is mentioned several times (page 1826, first full paragraph; page 1827, last but one sentence of the first full paragraph of the section "Side effects"; page 1828, second paragraph; page 1829, first and second full paragraphs). However, in spite of the warnings, D14 contains the indications that "When bacterial infection is the cause of an inflammatory reaction, steroids are commonly administered with appropriate antibacterial agents" (page 1828, second

paragraph, first sentence), that "Steroids are incorporated in intramammary products for use in bovine mastitis" (page 1828, second paragraph, third sentence), and that "The immunosuppressive actions of corticosteroids may increase the risk of infection unless antimicrobial therapy is provided" (page 1829, first full paragraph, last sentence). In addition it is commented that "Steroids effects are dose related, and it seems likely that historically some side effects have been overstated" while some results "were obtained using much higher dosages and concentrations of steroids than are achieved with therapeutically dosages in clinical studies" (page 1827, last but one paragraph).

4.5 In summary, while document D14 gives warnings related to the immunosuppressive action of steroids, it does not discourage using them in combination with antibiotics to treat mastitis. On the contrary it indicates that the combination is normally used for treatment of mastitis, underlines the importance of co-administering antibiotics in view of the immunosuppressive actions and informs that some warnings have been related to dosages that are much higher than the therapeutic ones. Document D14 does not support therefore the existence of a prejudice against using doses of prednisolone in the range of claim 1 of the main request.

4.6 Nothing more can be found in the other documents cited by the appellant. The crucial passage of D15 (paragraph bridging pages 441 and 442) is similar to the teaching of D14 in that, in spite of a warning, it is disclosed that corticosteroids are present in intramammary preparations in conjunction with an antibiotic and no dosage is given at which the use is discouraged. D16 is

a relatively old document in which, in spite of the general considerations on immunosuppression at high dosages at glucocorticoids (see e.g. page 898, paragraph bridging the two columns), no indication specific to mastitis and to doses used to treat it via intramammary administration is mentioned. For D17 and D18 no specific citation has been provided by the appellant and the Board does not see the need to add any further comment. In D19 it is mentioned that 0.04 mg/kg/day is a well-established experimental immunosuppressive dosage of dexamethasone for cattle (page 318, first full paragraph); however, an equivalent dose of prednisolone is not indicated and no mention is made of what happens in the presence of antibiotics. D20 is a very old paper dating back to 1968, whose content can be of no more relevance than a much more recent veterinary manual, such as D14, with regard to the existence of a prejudice at the relevant date.

4.7 On that basis it is concluded that the existence of a prejudice against increasing the dose of prednisolone to the range in claim 1 of the main request has not been demonstrated, so that the composition of the claim does not involve an inventive step.

Request not to admit auxiliary requests 1 to 24

5. Auxiliary requests 1 to 24 were filed by the appellant with the statement setting out the grounds of appeal. The respondent took position on these requests with the reply to the statement of grounds and requested not to admit the auxiliary requests only at the oral proceedings before the Board.

5.1 The Board does not see any justification in the late filing of the request of the respondent not to admit the auxiliary requests. In particular, the fact that the respondent took position on all the requests in the reply to the statement of grounds made it clear that it had no objection to their admittance at that stage and let the appellant believe with good grounds that the admittance of the requests would not be contested and that there was therefore no need to limit the number of requests, nor to reformulate them. A possible different intention of the respondent which could not be deduced from the facts available on file is in this respect not relevant. In view of that the Board does not see any cogent reason which could justify reopening an issue which was considered not disputed and therefore closed by the parties.

5.2 For these reasons the Board finds it appropriate not to admit the request of the respondent not to admit auxiliary requests 1 to 24 with the consequence that the auxiliary requests 1 to 11, 13 to 20 and 22 to 24 are in the proceedings (auxiliary requests 12 and 21 were withdrawn by the appellant).

Auxiliary requests - inventive step

6. Claim 1 according to auxiliary request 1 corresponds to granted claim 1 with the specification that "the composition comprises prednisolone in an amount of 20 to 40 mg / unit dose".

6.1 No evidence is available on file to show that the range "20 to 40 mg / unit dose" achieves any effect beyond what has been acknowledged for the range "at least 20 mg prednisolone / unit dose" (see point 3, above). Therefore the same problem is formulated as for claim 1

of the main request and the same analysis of obviousness (see point 4, above) applies. It is therefore concluded that claim 1 according to auxiliary request 1 does not involve an inventive step. The same conclusion holds for claim 1 of auxiliary requests 2 and 3 which have a wording identical to the one of claim 1 of auxiliary request 1.

7. In claim 1 according to auxiliary request 4 the range is further limited to "20 to 30 mg / unit dose".

7.1 Also in this case no evidence is available on file to show that the range "20 to 30 mg / unit dose" achieves any effect beyond what has been acknowledged for the range "at least 20 mg prednisolone / unit dose" (see point 3, above). It is therefore concluded that claim 1 according to auxiliary request 4 does not involve an inventive step for the same reasons as given for claim 1 of the main request (points 2 to 4, above). The same conclusion holds for claim 1 of auxiliary requests 5 and 6, which have a wording identical to the one of claim 1 of auxiliary request 4.

8. Claim 1 according to auxiliary request 7 corresponds to claim 1 according to auxiliary requests 1 with the addition that "the pharmaceutically acceptable carrier is an oily base".

8.1 No evidence is available as to the presence of a possible effect or advantage related to the choice of an oily base as pharmaceutically acceptable carrier, which is presented in the patent as a known option according to common practice (paragraph [0028]). In spite of the presence of a further distinguishing feature with respect to D12, namely the oily base as carrier, in the absence of further effects or

advantages the problem remains the same as for claim 1 of the main request (see point 3, above). As to obviousness, while the increase in the dose of prednisolone is not inventive for the same reasons as given above (see points 4 and 6), the choice of an oily base as pharmaceutically acceptable carrier is an arbitrary selection of a commonly known possibility, as acknowledged in the patent. It is therefore concluded that claim 1 according to auxiliary request 7 does not involve an inventive step. The same conclusion holds for claim 1 of auxiliary requests 8 and 9 which have a wording identical to that of claim 1 of auxiliary request 7.

9. Claim 1 according to auxiliary request 10 corresponds to claim 1 according to auxiliary request 4 with the addition that "the pharmaceutically acceptable carrier is an oily base".

9.1 As claim 1 of auxiliary request 10 contains the same amendment as auxiliary request 7, only with the dose of auxiliary request 4 instead of the dose of auxiliary request 1, the reasoning given for lack of inventive step of claim 1 of auxiliary requests 4 and 7 applies with the consequence that claim 1 according to auxiliary request 10 does not involve an inventive step for the reasons give above (points 4, 7 and 8). The same conclusion holds for claim 1 of auxiliary request 11, which has a wording identical to that of claim 1 of auxiliary request 10.

10. Claim 1 according to auxiliary request 13 corresponds to claim 1 according to auxiliary request 1 with the amendment of the antibiotic from "a cephalosporin" to "cephapirin".

10.1 No evidence is available on file to show that the choice of cephapirin brings effects or advantages additional to those acknowledged for claim 1 of auxiliary request 1. In spite of the fact that one difference with respect to D12 must be reformulated accordingly, nothing changes in the formulation of the solved problem and in the analysis of obviousness (points 3, 4 and 6 above). It is noted that if the advantages indicated by the appellant (cephapirin is active against gram positive bacteria and is amongst the antibiotics not banned for animals) are acknowledged, this can be done only on the basis of the common general knowledge with the consequence that these advantages may be taken into consideration in the formulation of the solved problem, but lack of inventive step results in any case in view of the same common general knowledge. It is therefore concluded that claim 1 according to auxiliary request 13 does not involve an inventive step. The same conclusion holds for claim 1 of auxiliary requests 14 and 15, which have a wording identical to that of claim 1 of auxiliary request 13.

11. Claim 1 according to auxiliary requests 16, 19 and 22 corresponds to claim 1 according to auxiliary requests 4, 7 and 10 respectively with the amendment of the antibiotic from "a cephalosporin" to "cephapirin".

11.1 Claim 1 according to auxiliary requests 16, 19 and 22 therefore introduces the same amendment as in claim 1 of auxiliary request 13, however in combination with the further amendments of the previous requests. As it has not been shown that the choice of the specific antibiotic has any effect in combination with the further amended features (the specific doses of prednisolone and the oily base as carrier) the same

reasoning as detailed for the previous requests (see points 3, 4, 7, 8, 9 and 10) applies with the consequence that claim 1 according to auxiliary requests 16, 19 and 22 does not involve an inventive step. The same conclusion holds for claim 1 of auxiliary requests 17 and 18, which have a wording identical to that of claim 1 of auxiliary request 16 and for claim 1 of auxiliary requests 20, 23 and 24, which have a wording identical to that of claim 1 of auxiliary request 19.

Conclusion

12. As claim 1 according to all the requests on file does not involve an inventive step, there is no need for the Board to decide on any other issue and the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani D. Boulois

Decision electronically authenticated