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Datasheet for the decision of 5 July 2018

Case Number: T 0644/14 - 3.3.07

Application Number: 03775738.2

Publication Number: 1581184

IPC: A61K9/06, A61K9/10, A61P31/04

Language of the proceedings: EN

Title of invention:
Veterinary compositions for treating mastitis

Patent Proprietor:
Zoetis UK Limited
Zoetis LLC

Opponents:
VIRBAC S.A.
Intervet International BV
Boehringer Ingelheim Vetmedica GmbH

Headword:
Veterinary compositions/ ZOETIS

Relevant legal provisions:
EPC Art. 104(1), 56, 123(2), 100(b), 54

Keyword:

Apportionment of costs - (no)
Inventive step - main request (no) - auxiliary request (yes)
Amendments - added subject-matter (no)
Novelty - auxiliary request (yes)
Sufficiency of disclosure - auxiliary request (yes)

Decisions cited:

G 0003/14

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Case Number: T 0644/14 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 July 2018

Appellant: (Patent Proprietor 1)	Zoetis UK Limited 5th Floor 6, St. Andrew Street London EC4A 3AE (GB)
Appellant: (Patent Proprietor 2)	Zoetis LLC 100 Campus Drive Florham Park NJ 07932 (US)
Representative:	Mannion, Sally Kim Zoetis UK Limited Walton Oaks Dorking Road Tadworth Surrey KT20 7NS (GB)
Appellant: (Opponent 1)	VIRBAC S.A. 1 ere Avenue, 2065M LID 06516 Carros (FR)
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Appellant: (Opponent 2)	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)

Appellant: (Opponent 3)	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Höfer, Friederike Dreikönigsgasse 10 D-89073 Ulm (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 27 January 2014 concerning maintenance of European patent No. 1581184 in amended form**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. European patent No. 1 581 184 was opposed by three opponents on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

The following documents were among those cited during the first-instance proceedings:

D1: GB 2 273 441
D5: WO 03/022245
D6: Journal of Dairy Science, 86:3899-3911, 2003
D7: Proceedings of the Minnesota Dairy Health Conference, 2003
D8: EP 271 306
D9: GB 1 456 349
D21: New Zealand veterinary journal, 46, 1998, 12-19
D22: GB 1 547 164
D33: Final study report filed by appellant-opponent 3, dated 12 August 2013
D34: Joint declaration of Mrs Quesnell and Mr Taube with annexes 1 to 4
D35: Irish Medicines Board Act 1995 - Orbenin® dry cow 500 mg Intramammary suspension
D36: Summary of product characteristics - Orbenin® Extra dry cow 600 mg

II. The appeals of the patent proprietors and of the three opponents lie against the decision of the opposition division according to which the subject-matter of auxiliary request 2 met the requirements of the EPC. The decision was based on the patent as granted and on two auxiliary requests filed during the oral proceedings held on 2 December 2013.

Independent claim 1 of the patent as granted read as follows:

"1. A veterinary composition for intra-mammary use in non-human animals comprising an antibacterial formulation and a separate seal formulation, wherein the antibacterial formulation is a vegetable oil-based formulation and the seal formulation comprises a gel base and a non-toxic heavy metal salt in the base in an amount of at least 30% by weight of the gel base".

In claim 1 of auxiliary request 1 it was specified that the gel base contained aluminium stearate and liquid paraffin. In claim 1 of auxiliary request 2 it was further specified that the vegetable oil was peanut oil and/or hydrogenated peanut oil.

III. According to the decision under appeal, document D1 was the closest prior art for the assessment of inventive step. The subject-matter of claim 1 of the patent differed from the disclosure of D1 in the use of a vegetable oil for formulation of the bacterial agent. The experimental evidence submitted by the patent proprietors was not sufficient to show that the improvement in terms of effectiveness of the teat seal was achieved over the whole scope of claim 1. The technical problem was the provision of an alternative formulation for veterinary use. D9 and D22 disclosed veterinary compositions comprising an antibacterial agent and a vegetable oil. The subject-matter of claim 1 was therefore obvious in view of the teaching of D1 in combination with D9 or D22.

The subject-matter of auxiliary request 1 was not inventive for substantially the same reasons as the main request.

With regard to auxiliary request 2, relating to formulations containing peanut oil, the opposition division considered that the experiments submitted by the patent proprietors credibly demonstrated that the teat seal maintained its integrity over the dry cow period. The technical problem was the provision of an antibiotic composition showing teat seal integrity over the dry cow period. Document D1 taught that aqueous formulations were better than oily formulations. Thus, the skilled person would not have considered the use of peanut oil. The subject-matter of auxiliary request 2 was therefore inventive.

IV. In the statement setting out the grounds of appeal filed on 6 June 2014 the appellant-patent proprietors defended their case on the basis of the patent as granted and thirteen auxiliary requests.

With the reply to the appeals of the opponents, submitted on 24 November 2014, the appellant-patent proprietors filed eleven new auxiliary requests partly replacing the auxiliary requests already on file.

The relevant requests in the context of the present decision are the main request (patent as granted) and the four highest-ranking auxiliary requests, which have been designated AR1, AR1', AR1'A and AR1''.

Claim 1 of AR1, filed on 6 June 2014, read as follows:

"1. Use of a veterinary composition comprising an antibacterial formulation and a separate seal

formulation, wherein the antibacterial formulation is a vegetable oil-based formulation and the seal formulation comprises a gel base and a non-toxic heavy metal salt in the base in an amount of at least 30% by weight of the gel base, in the manufacture of a medicament for the treatment or prophylaxis of mammary disorders in non-human animals".

Claim 1 of AR1', filed on 24 November 2014, was identical to claim 1 of the patent (see point II above).

Claim 1 of AR1'A, filed on 6 June 2014, was identical to claim 1 of AR1.

Claim 1 of AR1'', filed on 24 November 2014, was based on claim 1 of the patent and differed therefrom in specifying that the vegetable oil-based formulation was a peanut oil or peanut oil and hydrogenated peanut oil-based formulation.

V. The following document was submitted by appellant-opponent 3 during the appeal proceedings with the statement setting out the grounds of appeal:

D41: Declaration of Ms Abbeloos

VI. In a communication pursuant to Article 15(1) RPBA issued on 15 May 2018 the Board commented *inter alia* on the experimental results disclosed in the patent and in D34, expressing its concerns as to whether the positive results shown for formulations containing an oil derived from peanuts could also be obtained when other vegetable oils were used.

VII. Oral proceedings were held on 5 July 2018. They were attended only by the appellant-patent proprietors. Appellant-opponents 1 and 3 had previously announced that they would be absent.

VIII. The arguments presented in writing by the appellant-opponents, where relevant to the present decision, may be summarised as follows:

(a) Document D34, containing some experimental data, was submitted by the appellant-patent proprietors just one month before the oral proceedings before the opposition division. There was no possible justification for the late filing of this document, as the experiments had been performed in 2002. Thus, the opposition division's decision to admit this document was to be overturned. Furthermore, the Board was requested to order an apportionment of costs.

(b) The claims of all the requests included expressions such as "oil-based formulation" or "gel-based on aluminium stearate" which were not sufficiently clear.

(c) According to paragraph [0020] of the description, the co-administration of a vegetable oil-based formulation in conjunction with a seal formulation had the effect of increasing the amount of seal present in the teat canal. However, there was no evidence that this effect was achieved over the whole scope of the claim. Thus, the invention was not sufficiently disclosed. Furthermore, the description did not provide any information as to the amount of vegetable oil or peanut oil included in the formulations.

(d) Documents D6 and D7 described an experimental study carried out before the priority date of the patent. This study represented a prior use that anticipated the subject-matter of some requests. Document D5 was also novelty-destroying.

(e) Document D1 was the closest prior art for the assessment of inventive step. The compositions of the opposed patent and of the auxiliary requests differed from composition 2A6 of D1 in that the antibiotic was formulated in a vegetable oil-based composition or a peanut oil-based composition, whereas D1 did not indicate which oil was used in composition 2A6. There was no evidence that the effect of maintaining seal integrity over the dry period was achieved over the whole scope of the claim. In particular, there were no experiments relating to formulations containing a vegetable oil different than an oil derived from peanuts. The vegetable oils were a heterogeneous class of substances having different properties. The experiments disclosed in D34 did not show any clear improvement over the composition of D1, not even for compositions based on peanut oil. Indeed, according to the data on page 11 of D1 the effective seal duration was more than 47 days. The experiments of D34 did not allow a direct comparison with the results of D1. In any case, there was no evidence in D34 for an effective seal duration longer than 47 days. The experimental report submitted by appellant-opponent 3 (D33) confirmed that there was no improvement over the composition of D1. Some deficiencies included in this report were dealt with and clarified in the declaration of Ms Abbeloos (D41). Accordingly, the

technical problem over D1 was to be seen in the provision of an alternative composition for intra-mammary use. It was not correct, as maintained by the appellant-patent proprietors, that based on the content of D1 there was a technical prejudice against the use of oil-based formulations. Quite to the contrary: several documents such as D8 and D9 suggested formulating the antibiotic in a vegetable oil-based composition and preferably in a peanut oil-based composition. Thus, the subject-matter of the patent and of the auxiliary requests did not involve an inventive step. This conclusion also held good when starting from document D21 as the closest prior art.

IX. The arguments of the appellant-patent proprietors, where relevant to the present decision, may be summarised as follows:

(a) Experimental report D34 had been filed in response to the experimental data submitted by appellant-opponent 3. The opposition division's decision to admit D34 into the proceedings was therefore correct.

(b) The claims of all the requests met the requirement of clarity. Moreover, the features contested by the appellant-opponents were already present in the patent as granted. Thus, they were not open to an attack under Article 84 EPC.

(c) Antibacterial formulations based on vegetable oil or peanut oil had been well known in the art before the filing date of the patent. The same was true of the teat seal formulations. Accordingly, the skilled person would have had no problems in

preparing the compositions claimed in all the requests. For this reason alone, the requirement of sufficiency of disclosure was met.

(d) The exact composition of the products used in the experiments described in D6 and D7 was not clear. Thus, these experiments did not anticipate the subject-matter of the claims. Starting from the disclosure of D5, several selections were required in order to arrive at the subject-matter of claim 1 of the present requests. Thus, the claims were novel over D5 as well.

(e) The technical problem over document D1 was to be seen in the provision of a composition which allowed seal integrity to be maintained over the dry period. The teaching of D1 was to avoid the use of an oil-based composition for the antibiotic. There was a clear suggestion to use an aqueous-based formulation instead. The experiments disclosed in the patent showed that three formulations containing vegetable oil were better than the control compositions. This result was surprising in view of the teaching of D1. There was no reason to doubt that the data presented in the patent could be extrapolated to any other vegetable oil-based composition. The experiments of D34 concerned compositions in which the antibiotic formulation was based on peanut oil. The results disclosed in appendix 4 of D34 indicated that in 91% of the experiments the seal composition was still present after 49 days. Such a long duration of seal integrity went against the observations made in D1 and could not be predicted on the basis of the available prior art.

X. The appellant-patent proprietors requested that the decision under appeal be set aside and that the opposition be rejected (i.e. that the patent be maintained as granted), or alternatively that the patent be maintained on the basis of one of the following auxiliary requests (AR):

AR1, AR1', AR1'A, AR1'', AR1''A, AR1''', AR1'''A, AR2, AR2A, AR3, AR3A, AR4, AR4A
These requests were to be considered in the above order. AR1 and AR1'A had been filed on 6 June 2014 with the statement setting out the grounds of appeal, and the remaining requests had been filed on 24 November 2014. The appellant-patent proprietors further requested that appellant-opponent 2's request for an apportionment of costs be rejected.

XI. Appellant-opponents 1, 2 and 3 had requested in writing that the decision under appeal be set aside and the patent revoked. Appellant-opponent 2 had further requested the Board to overturn the opposition division's decision admitting document D34 and to decide on an apportionment of costs in favour of the opponents in view of the late filing of this document.

Reasons for the Decision

Admission of document D34 - Request for apportionment of costs

1. The opposition division decided to admit the experimental data filed by the appellant-patent proprietors on 31 October 2013 (document D34) since they had been filed in response to the filing of experimental report D33 and since they were *prima facie*

relevant (point 3.4 of the opposition division's decision).

1.1 Thus, the opposition division exercised its discretion under Article 114 EPC by applying the correct criteria, and there is no indication that this was done in an unreasonable way. Furthermore, the Board agrees with the opposition division that D34 is *prima facie* relevant and was filed in response to the filing of D33.

Hence, the Board sees no reason to overrule the opposition division's decision to admit document D34 and its annexes.

1.2 D34 was filed in response to the filing of D33 by opponent-3. This was a legitimate reaction from the side of the appellant-patent proprietors. Under these circumstances, the Board cannot discern any misconduct which would justify a different apportionment of costs (Article 104 EPC).

Main request (patent as granted)

2. Inventive step

2.1 The invention underlying the patent in suit relates to the treatment of mastitis in mammals, in particular in cows (paragraph [0001]). More specifically the invention concerns compositions comprising two parts, namely a seal formulation that provides a physical barrier in the teat canal and an antibacterial formulation (paragraphs [0002] to [0008]). The description of the patent stresses that an important property of the teat seal is that it should remain *in situ* for the entire duration of the dry cow period,

i.e. the non-lactating period of at least 40 days prior to calving.

2.2 Closest prior art

2.2.1 The Board agrees with the opposition division that document D1 is the closest prior art. This document in the passage linking pages 10 and 11 ("Injector type 2A - Study 3") discloses the use of a teat seal containing bismuth subnitrate in combination with an aqueous-based antibiotic formulation or an oily-based formulation (formulation 2A6).

The subject-matter of the patent differs from the disclosure of D1 relating to the combined use of a teat seal and an oil-based antibiotic formulation in the selection of a vegetable oil as excipient for the antibiotic formulation.

2.2.2 Document D21, proposed by appellant-opponent 3 as alternative closest prior art, is less close to the subject-matter of the patent than D1, in that it relates to a treatment in which the antibiotic is in aqueous formulation (see page 13, right-hand column, first paragraph). Thus, D1 is a more suitable starting point for the assessment of inventive step.

2.3 Technical problem

2.3.1 In document D1 it is observed that a combination of seal and aqueous-based antibiotic provides better results, in terms of effective seal duration (ESD) and bismuth subnitrate (BSN) recovery (i.e. seal recovery), than a combination of seal and oil-based antibiotic (page 11, lines 7 to 10). According to the data provided on page 11, when an oil-based antibiotic is

used (formulation 2A6) the BSN recovery after 47.8 days is 0%, whereas when an aqueous-based antibiotic formulation is used (formulation 2A6[1]) the BSN recovery after 63.3 days is 75.2%.

The appellant-patent proprietors essentially argue that by combining a seal formulation with a vegetable oil-based antibiotic formulation it is possible to obtain a prolonged antibacterial activity and seal integrity. This would be surprising having regard to the poor results shown in D1 when an oil-based antibiotic is used.

2.3.2 In order to demonstrate this effect the appellant-patent proprietors essentially rely on the data disclosed in experimental report D34 and in the patent.

Document D34 relates to a study involving the treatment of more than 20 cows with a seal containing bismuth subnitrate (Orbeseal®) in combination with a peanut oil-based antibiotic. Appendix 4 of the report shows that in 91% of the cases the seal is still present in the teat cistern after 49 days.

The patent in paragraph [0020] describes an experiment in which a cow received three antibiotic formulations, each placed in a separate teat. One of the antibiotic formulations (Formulation A) contained a mixture of peanut oil and hydrogenated peanut oil, whereas the other formulations (Formulations B and C) contained peanut oil. Each of the three teats was then sealed with a bismuth-based teat seal. The fourth teat received only the bismuth-based seal formulation (reference treatment). The teats were assessed by X-ray analysis to determine the area of opacity due to the

presence of bismuth, which is proportional to the seal integrity. Table 1 provides the following results in terms of averaged area of opacity (AAO):

	Teat 1	**Teat 2**	**Teat 3**	**Teat 4**
Antibiotic	None	Formulation A	Formulation B	Formulation C
AAO	1.0	1.1	1.7	1.6

In the comments following Table 1 it is emphasised that in Formulations A to C the vegetable oil-based antibiotic formulation in conjunction with the seal formulation surprisingly leads to an increase in the amount of seal present at the base of the teat canal (paragraph [0021]).

2.3.3 It follows from the above that both D34 and the patent relate to experiments in which the antibiotic was formulated in an oil derived from peanuts, i.e. peanut oil or a mixture of peanut oil and hydrogenated peanut oil. Thus, the question that arises when assessing these experiments in the context of defining the technical problem is whether the results obtained with formulations containing peanut oil or hydrogenated peanut oil can be extrapolated to the whole class of vegetable oils.

In this regard the Board observes that Table 1 of the patent indicates that the formulation comprising a mixture of peanut oil and hydrogenated peanut oil (Formulation A) provides very different results in terms of seal integrity than the formulations comprising only peanut oil (Formulations B and C). Indeed, although the AAOs of each of the three formulations A to C is higher than the AAO of the reference treatment, which is an indication of good

seal integrity, the AAO of Formulation A is only about 65% of the AAO of Formulation B and only about 69% of the AAO of formulation C.

Peanut oil and hydrogenated peanut oil are structurally very similar, in that they differ only in the number of double bonds. Hence, the results of the patent indicate that, within the class of vegetable oils, even minor modifications of the chemical structure may have an impact on the effectiveness of the product. At the same time the Board observes that the expression "vegetable oils" encompasses a broad class of substances which may have different chemical structures. This suggests that the difference in terms of AAO observed within the small group of oils derived from peanuts could even be amplified when the broader and more heterogeneous class of all the vegetable oils is considered.

2.3.4 As discussed in point 2.3.1 above, D1 reports poor results in terms of seal integrity for a treatment involving the use of an oil-based antibiotic. In these circumstances, the appellant-patent proprietors bear the burden of providing convincing evidence that, contrary to the teaching of D1, an entire class of oils, namely the vegetable oils, can be used for the preparation of antibiotic formulations that when used in conjunction with a seal provide good results in terms of seal integrity.

For the reasons set out above, the Board considers that the appellant-patent proprietors have not provided convincing evidence that the results achieved with formulations containing peanut oil or hydrogenated peanut oil can also be achieved with formulations containing a different vegetable oil.

In other words, there is no evidence that an improved effect over the formulation of D1 is obtained throughout the entire scope of claim 1.

2.3.5 The objective technical problem is therefore defined as the provision of an alternative composition for intra-mammary use comprising an antibacterial formulation and a separate seal formulation.

2.4 Obviousness

2.4.1 The use of vegetable oils in the preparation of antibiotic formulations useful in the treatment of bovine mastitis is known in the prior art. For instance, document D9 describes antibiotic compositions containing peanut oil (examples 1 to 4).

Hence, the skilled person facing the problem of providing an alternative to the treatment disclosed in D1 would arrive without any inventive effort at the idea of preparing a composition corresponding to formulation 2A6 of D1 in which the antibiotic is formulated in a vegetable oil.

Thus, the subject-matter of claim 1 of the patent in suit does not fulfil the requirements of Article 56 EPC.

Auxiliary requests AR1, AR1' and AR1'A

3. Claim 1 of each of these requests relates to compositions or the use of compositions that comprise an antibacterial formulation and a separate seal and wherein the antibacterial formulation is a vegetable oil-based formulation.

The considerations set out in point 2 above in relation to the inventive step of the patent also apply to the subject-matter of claim 1 of these requests.

Hence, auxiliary requests AR1, AR1' and AR1'A do not comply with the requirement of Article 56 EPC.

Auxiliary request AR1''

4. Article 123(2) EPC

4.1 The appellant-opponents did not raise any objection under Article 123(2) EPC specifically against the amendments introduced in this request.

The Board notes that the subject-matter of claim 1 is based upon the introduction in claim 1 as filed of the feature disclosed in claim 8 whereby the oil used for the antibiotic formulation is peanut oil or peanut oil and hydrogenated peanut oil. Claims 2 to 4 correspond to original claims 3 to 7, and claims 5 to 9 correspond to original claims 7 to 11.

4.2 Hence, the subject-matter of auxiliary request AR1'' fulfils the requirements of Article 123(2) EPC.

5. Clarity

5.1 The appellant-opponents referred to several potential issues of clarity (see point VIII(b) above).

The Board notes that none of these potential issues arises from amendments made after the granting of the patent. Therefore, in application of the principles affirmed in decision G 3/14 (OJ EPO 2015, A102), these objections as to lack of clarity cannot be examined in

the present opposition appeal proceedings.

6. Sufficiency of disclosure

6.1 As observed in the appealed decision, the patent indicates which components can be used in the antibacterial formulation and in the seal formulation. Moreover, these formulations are part of the state of the art (see e.g. example 1 of D9 and formulation 2A4 of D1). Hence, the skilled person would have no difficulty in preparing the single formulations of the veterinary composition.

6.2 The Board further notes that the claims do not contain any feature requiring the veterinary compositions to have a "minimum level" of effectiveness. Hence, the fact that formulation A in table 1 of the patent provides poor results in terms of area of opacity compared to formulations B and C does not amount to a problem of sufficiency of disclosure.

6.3 It follows from the above that auxiliary request AR1'' meets the requirements of sufficiency of disclosure.

7. Novelty

7.1 Post-published documents D6 and D7 relate to a study concerning the effectiveness in the prevention of intra-mammary infections of an internal teat seal used in combination with an intra-mammary antibiotic. The antibiotic used is Orbenin®-DC containing cloxacillin as active ingredient (see D6, section "Dry-off enrollment, treatment assignment, and sampling strategy", page 3900). The enrollment of the cows for the study took place between March and August 2002 (see D6, "Results", page 3903).

The appellant-opponents base their objection of lack of novelty on the public prior use represented by the experimental study referred to in D6 and D7.

7.2 As noted by the appellant-patent proprietors, D6 and D7 fail to provide information as to the composition of the product Orbenin®-DC. Documents D35 and D36 indicate that the commercial name Orbenin®-DC has also been used for mineral oil-based compositions. Thus, there is no clear evidence that the study disclosed in D6 and D7 involved the use of a peanut oil or peanut oil and hydrogenated peanut oil-based formulation.

Thus, the experimental study reported in D6 and D7 does not anticipate the subject-matter of auxiliary request AR1''.

7.3 As to the objection of lack of novelty in view of document D5, it is noted that this document does not disclose any composition comprising a seal and an antibacterial formulation in which the antibacterial formulation contains peanut oil or peanut oil and hydrogenated peanut oil.

7.4 It follows that auxiliary request AR1'' fulfils the requirement of novelty.

8. Inventive step

8.1 Claim 1 of auxiliary request AR1'' differs from claim 1 of the patent in specifying that the antibacterial formulation is a peanut oil or peanut oil and hydrogenated peanut oil-based formulation.

8.2 As discussed in point 2.3.2 above, experimental report D34 reports the results of a study in which more than 20 cows were treated with a seal containing bismuth subnitrate (Orbeseal®) in combination with a peanut oil-based antibiotic. Appendix 4 of D34 shows that in 91% of the cases the seal is still present in the teat cistern after 49 days. These results represent a clear improvement over the results disclosed on page 11 of D1 with regard to formulation 2A6, a composition comprising a seal and an antibiotic formulation suspended in an undefined oil. In that case it was observed that 47.8 days after administration of the composition the seal was no longer present in the teat canal.

Positive results for products in which the antibiotic is formulated in an oil derived from peanuts are reported in the patent as well (see point 2.3.2 above). However, the parameter measured in the test disclosed in the patent (AAO) does not allow any direct comparison with the results disclosed in D1.

8.3 During the first-instance proceedings an experimental report was also submitted by appellant-opponent 3 (document D33). One of the experiments described in this document (test "IVP3") relates to the treatment of a cow with a seal and a peanut oil-based formulation. The results disclosed for this treatment diverge from those disclosed in D34. Indeed, in paragraph 16.4.2 of D33 it is observed that from the seventh day after treatment the X-ray pictures show a reduction in the density of the opacity, which indicates a degradation of the seal.

8.4 In comparing the experiments submitted by appellant-opponent 3 (D33) with those of the

appellant-patent proprietors (D34), the Board notes that in D33 a single animal was treated with a peanut oil-based formulation, whereas in D34 more than 20 animals received the same type of treatment. The results of D33 are therefore less relevant, from a statistical point of view, than the results disclosed in D34. In this respect it is also noted that the authors of D33 do not exclude an "animal related effect" in relation to the IVP3 treatment (paragraph 16.4.3). In relation to all the experiments the authors of D33 also acknowledge that X-ray image acquisition involved several problems due to the movement of the animals (paragraph 11.1).

Furthermore, as noted by the appellant-patent proprietors the data of D34 suggest a degradation of the seal even when no antibiotic formulation is administered. This failure is unexpected, since a seal is expected to reside in the teat canal for long periods. According to the authors of D34 there was something wrong with the administration of the control treatment (i.e. the teat seal) that could demonstrate an inappropriate use of this product (point 6.c of D34). In the expert declaration filed by appellant-opponent 3 during the appeal proceedings (document D41) it is acknowledged that the failure of the control treatments is remarkable and unexplained (D41, page 4).

8.5 In the light of the considerations set out in the previous paragraph the Board concludes that experimental report D33 does not call into question the validity of the experiments disclosed in D34 and the conclusion that the compositions of claim 1 are better than composition 2A6 of D1 in terms of duration of seal integrity.

The technical problem with regard to auxiliary request AR1'' is therefore the provision of a composition for intra-mammary use comprising an antibacterial formulation and a separate seal formulation that preserves the integrity of the seal.

8.6 The disappointing results disclosed in D1 for formulation 2A6 would have dissuaded the skilled person from considering the combination of a seal with an oily-based antibiotic formulation. He would rather have opted for an aqueous-based antibiotic formulation in view of the good results achieved with formulation 2A6[1] (see point 2.3.1 above).

8.7 As pointed out by the appellant-opponents, peanut oil-based formulations are disclosed in various prior-art documents such as D8 and D9. However, these documents do not describe treatments in which the antibiotic is co-administered with a seal. Hence, these documents do not provide any relevant teaching to the skilled person faced with the problem of providing antibiotic formulations that do not cause seal integrity to deteriorate.

Hence, none of the cited documents indicates that the use of a peanut oil-based antibiotic formulation provides good results in terms of seal integrity throughout the dry period. Accordingly, the skilled person would not arrive at the subject-matter of claim 1 in an obvious manner.

8.8 This conclusion also holds good when starting from document D21 as closest prior art. As mentioned in point 2.2.2 above, this document relates to a treatment in which the antibiotic is in aqueous formulation. In the Board's view, having regard to the teaching of

document D1 the skilled person would never have considered replacing the aqueous antibiotic formulation with an oily-based formulation in the composition of D21.

8.9 In the light of the considerations set out above, the Board concludes that the subject-matter of auxiliary request AR1'' meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims of auxiliary request AR1'' filed by letter of 24 November 2014 and a description to be adapted thereto.

3. Appellant-opponent 2's request for an apportionment of costs is rejected.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated