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Datasheet for the decision of 21 March 2007

Case Number: T 0028/06 - 3.3.02

Application Number: 97949079.4

Publication Number: 0971690

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Antiinfective free intramammary veterinary composition

Patentee:
Bimeda Reserach & Development Limited

Opponents:
VIRBAC S.A.
Akzo Nobel N.V.

Headword:
Veterinary formulation/BIMEDA RESEARCH & DEVELOPMENT LIMITED

Relevant legal provisions:
EPC Art. 84, 123, 100b, 54

Keyword:
"Main request - remittal for inventive step assessment"

Decisions cited:
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Catchword:
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Case Number: T 0028/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 21 March 2007

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 11 November 2005 revoking European patent No. 0971690 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

I. European patent N° 0 971 690 based on application N° 97 949 079.4 was granted on the basis of 26 claims.

Independent claims 1, 8, 9 and 17 as granted read as follows:

1. An anti infective-free seal formulation comprising a non-toxic heavy metal salt in a gel base providing a physical barrier in a teat canal for prophylaxis of intramammary infection.

8. Use of an anti infective-free seal formulation as claimed in any of claims 1 to 7 which does not contain an anti-infective, in the preparation of a medicament for use in forming an anti-infective free physical barrier in the teat canal for prophylactic treatment of mammary disorders in non-human animals during an animals dry period.

9. Use of an anti infective-free seal formulation in the preparation of a medicament for forming a physical barrier in the teat canal for prophylactically controlling infection of the mammary gland in non-human animals by a mastitis – causing organism.

17. A process for preparing an anti infective-free seal formulation as claimed in claim 1 comprising the steps of adding a non-toxic heavy metal salt to a gel base in at least two separate stages.

II. Oppositions were filed against the granted patent by opponents 1 and 2. The patent was opposed under

Article 100(b) EPC for insufficiency of disclosure, under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(c) for added matter extending beyond the content of the application as filed.

The following documents *inter alia* were cited during the proceedings:

(1) IE-A-930947

(2) WO 94/1 3261

(3) W0-A-9531180

(4) GB-A-2273441

(5) GB-A-273443

(6) GB-A-2273655

(11) W.J. Meaney "Effect of a dry period teat seal on bovine udder infection" Ir. J. agric. Res. 16: 293-299, 1977.

(14) Ouvrage: "Disinfection, Sterilization and Preservation" Third Ed. by Seymour S. Block, Chap. 17-19, p. 346-398, 1983.

(39) Report entitled "A study of the anti-infective properties of teat seal formulations in the presence and absence of acriflavine".

(40) Article from Pro Agri September 1996

(41) English Translation of Pro Agri Article

III. The decision of the Opposition Division revoked the patent under Article 102(1) EPC.

The Opposition Division took the view that the main request and the auxiliary request fulfilled the requirements of Article 123 EPC.

It was also of the opinion that the granted patent fulfilled the requirements of Article 100(b) EPC, as the objections raised by the opponents concerned in fact clarity and did not prevent the skilled person from reworking the claimed invention.

However, the Opposition Division rejected the main request relating to a first medical use, because its subject-matter was anticipated by, among other things, the disclosure in document (4).

It rejected the auxiliary request relating to a second medical use on the basis of the same document.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 21 March 2007.

During the appeal proceedings the appellant filed a new main request of 15 claims as single request in replacement of all the previously filed requests.

Independent claims 1 and 7 of this request read:

1. Use of a seal formulation, comprising bismuth subnitrate, but no other anti-infective in a gel base, in the preparation of a medicament for forming a physical barrier in the teat canal for prophylactically controlling infection of the mammary gland in a non-human animal by a mastitis – causing organism, said prophylaxis does not involve the use of an antibiotic.

7. A process for preparing a seal formulation, comprising bismuth subnitrate, but no other anti-infective, in a gel base, comprising the steps of adding bismuth subnitrate to the gel base in at least two separate stages.

VI. As to Article 84 EPC, the appellant expressed the view that all the terms used in the newly filed claims were common terms in the field, so that the skilled person would have no problems understanding the claims.

It further argued that the new set of claims had a basis in the original application as filed and that it did not contravene Article 123(3) EPC as the claims were based on the claims as granted.

Concerning the objections relating to Article 100(b) EPC, it repeated the conclusions of the Opposition Division that these were in fact unfounded clarity objections, which did not put into question the feasibility of the claimed subject-matter.

It also submitted that the wording of claim 1 made it clear that no anti-infective other than bismuth

subnitrate was present in the formulation, which in its opinion restored the novelty of the subject-matter of claim 1 vis-à-vis the available prior art documents, which disclosed a formulation containing subnitrate and acriflavine, ie a further anti-infective.

VII. The respondents contested the clarity of claim 1 because the terms "antibiotic" and "anti-infective" were not defined in the patent, which led to contradictions, and because the feature in claim 1 "said prophylaxis does not involve the use of an antibiotic" did not precisely indicate when an antibiotic can not be used.

They argued that claim 1 was not disclosed in the application as originally filed because it did not disclose "a seal formulation comprising bismuth subnitrate, but no other anti-infective".

In their opinion, claim 1 also contravened Article 123(3) EPC because the granted claims did not cover embodiments containing anti-infective.

As to Article 100(b) EPC, they contended that the patent did not contain any teaching on how to prepare gel formulations containing bismuth subnitrate other than the one in the example.

They submitted that the subject-matter of claim 1 was anticipated by the disclosure in documents (1) to (6) and in document (11) because acriflavine was not used as anti-infective but as pigment in the formulations of these documents and because its amount was not sufficient to be effective as anti-infective.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division with the set of claims of the main request filed during oral proceedings.

The respondents requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. Admissibility of documents (40) and (41) of respondent 2 and of the experimental report (39) of the appellant.

Documents (40) and (41)

The main rule is that all requests and documents have to be in the grounds of appeal (Article 10c RPBA).

According to the jurisprudence of the Board, new requests and documents are admissible if they are a direct reaction to new arguments or new points of discussion.

That is applicable in this case, as respondent 2 indicated during the oral proceedings that it wanted to rely on these documents, filed with a letter dated 6 March 2007, ie 15 days before the oral proceedings, only with respect to the assessment of inventive step.

Since, as indicated by the Board in its communication to the parties of 7 March 2007, inventive step was not

within the scope of the oral proceedings, the Board sees no reason to admit these documents into the proceedings.

Experimental Report (39)

According to the appellant, although this project was started directly after the Opposition Division's decision, this report could not be submitted earlier than the 12 February 2007, ie 6 weeks before the oral proceedings, because of the complicated nature of the experiments and because of the difficulties encountered in finding an adequate laboratory.

The Board observes that, under these circumstances, as argued by the respondents, it was then not possible for the respondents to react to these experimental data within six weeks.

Accordingly, it is not admitted into the proceedings.

In that respect, the Board also notes that the appellant did not indicate during the appeal procedure that such complicated experiments were being carried out, in particular not after the summons to attend oral proceedings, so that neither the parties, nor the Board had a chance to consider the possibility of the postponement of the oral proceedings.

3. *Article 84 EPC*

The Board agrees with the respondents that the terms "antibiotic" and "anti-infective" are not defined in the patent in suit.

As pointed out by the appellant, the Board notes however that these terms are usual terms, commonly and frequently used in the field of pharmaceutics for defining different chemical compounds. Accordingly the Board sees no reason why the skilled person would not give these terms their normal meaning, the more so since the description does not provide any hint for a different understanding.

As to the contradiction between claim 1, requiring the absence of the anti-infective other than bismuth subnitrate, and claim 5, reciting that aluminium stearate is present in the gel, the Board notes that document (14) does not disclose that aluminium stearate has anti-infective properties.

In fact, the only aluminium derivatives disclosed in this document are aluminium trichloride and aluminium sulphate (tables 19-1 and 19-2).

Accordingly, under the present circumstances, the Board has no reason not to accept the appellant's argumentation that organic aluminium stearate, which is structurally unrelated to the disclosed inorganic salts, does not possess anti-infective properties.

Concerning the lack of clarity of the feature "said prophylaxis does not involve the use of an antibiotic", the Board does not see any difficulties in understanding this feature which, according to the wording of claim 1, can relate to the period of prophylaxis achieved by sealing the teat canal.

In other words, claim 1 merely requires that while the teat canal is sealed with the gel formulation for prophylactically controlling infection no antibiotic can be used.

Therefore, it appears that the skilled person would have no difficulty in knowing whether an embodiment would fall within the scope of claim 1 of the contested patent, so that the Board concludes that the requirements of Article 84 EPC are fulfilled.

No objections were raised with respect to the remaining claims and the Board sees no reason to differ.

4. *Article 123 EPC*

Article 123(2) EPC

Claim 1 requires, in its first part, the "use of a seal formulation comprising bismuth subnitrate, but no other anti-infective in a gel base, in the preparation of a medicament for forming a physical barrier in the teat canal"

Claims 1, 2 and 6 as originally filed reads:

1. An anti infective-free formulation for prophylaxis of intramammary infection comprising a seal formulation to provide an anti infective-free physical barrier in the teat canal.

2. A formulation as claimed in claim 1 wherein the seal formulation comprises a non-toxic heavy metal salt in a gel base.

6. A formulation as claimed in any of claims 2 to 5 wherein the salt is bismuth sub-nitrate.

Accordingly, since bismuth sub-nitrate is a product having anti-infective properties, the only sensible reading of claim 6 in combination with claims 1 and 2 as originally filed corresponds precisely to the wording of claim 1 filed during the oral proceedings.

This reading of the claims is also not contradicted by the example or other parts of the description since no other anti-infectives are disclosed therein.

The second part of claim 1 recites that the physical barrier is "for prophylactically controlling infection of the mammary gland in a non-human animal by a mastitis – causing organism, said prophylaxis does not involve the use of an antibiotic"

Support for these features is to be found on page 2, paragraph 4 of the application as originally filed which reads:

The invention also provides **a prophylactic method of controlling the infection of the mammary gland by a mastitis-causing organism** by sealing the gland with a seal formulation to provide a physical barrier in the teat canal.

and, for instance, under "statement of invention", first paragraph which reads:

"We have found that if a physical barrier is provided with the teat canal/and or the lower teat sinus during the dry period **without the use of antibiotics**, the incidence of mammary disorders is substantially reduced. This is very surprising as all conventional treatments involve the use of antibiotics. **Because no antibiotics are required** very substantial advantages result, without any significant reduction in effectiveness.".

The feature "in non-human animal" is disclosed on page 2, line 14.

Accordingly, the Board does not agree with the respondents that claim 1 is not disclosed in the application as originally filed.

No objections were raised with respect to the remaining claims and the Board sees no reason to differ.

Article 123(3) EPC

Claims 9, 10 and 14 as granted read:

9. Use of an anti infective-free seal formulation in the preparation of a medicament for forming a physical barrier in the teat canal for prophylactically controlling infection of the mammary gland in non-human animals by a mastitis – causing organism.

10. Use as claimed in claims 8 or 9 wherein the seal formulation comprises a non-toxic heavy metal salt in a gel base.

14. Use as claimed in any of claims 8 to 13 wherein the salt is bismuth sub-nitrate.

Accordingly, since bismuth sub-nitrate is a product having anti-infective properties, the only sensible reading of claim 14 as granted in combination with claims 9 and 10 corresponds precisely to the wording of claim 1 filed during the oral proceedings.

This reading of the claims is also not contradicted by the example or other parts of the description since no other anti-infectives are disclosed therein.

Therefore, contrary to the respondents' view the subject-matter of claim 1 of the request presented during the oral proceedings was already in the set of claims as granted and it does not contravene Article 123(3) EPC.

No objection were raised with respect to the remaining claims and the Board sees no reason to differ.

5. *Article 100(b) EPC*

Beside the objections relating to clarity which were repeated with respect to Article 100(b) EPC (see point 3 above) and the allegation that there is a lack of teaching for preparing further gels, the only new argument brought by the respondent was based on the assumption that the term anti-infective used in the claims referred to a functional definition rather than to the mere indication of the known properties of a product, which would then require the disclosure in the application as originally filed of a test and of

specific conditions to determine whether this functional definition is fulfilled.

The Board sees however no reason for such a reading of the claim since the wording in the claim does not refer to an "effective" anti-infective but merely to anti-infective. The more so, since there is no hint in the patent in suit for a different understanding.

Under these circumstances and in the absence of concrete evidence or verifiable facts to the contrary, the Board concludes that the requirements of Article 100(b) EPC are fulfilled and in particular that there is no undue burden in preparing further gels comprising, for instance, different gel bases, or different ingredient amounts.

6. *Article 54 EPC*

6.1 Document (4) has been cited under Article 54 EPC as prejudicial to the novelty of the subject-matter of the patent in suit.

Document (4)
It describes a seal formulation **comprising** a gel base and bismuth subnitrate (claims 1, 4 and 16; page 1, lines 20 to 24).

Injectors 2A and 2B disclose the ingredients used in the seal formulation. It appears that acriflavin is always present in the formulations shown.

The seal formulation provides a barrier to the ingress of pathogens in the teat canal (page 1, lines 20 to 24;

page 5, lines 26 to 28). In the context of the document which relates to compositions for the prophylaxis and treatment of mastitis in dry cows, this is, for the skilled person, a clear disclosure of the prophylactic effect of the seal formulation **as such** vis-à-vis microbial infection of the mammary gland by a mastitis-causing organism without antibiotic (page 2, first paragraph).

Accordingly, the use of a seal formulation comprising bismuth subnitrate in a gel base, in the preparation of a medicament for forming a physical barrier in the teat canal for prophylactically controlling infection of the mammary gland in non-human animals by a mastitis – causing organism, wherein said prophylaxis does not involve the use of an antibiotic is implicitly disclosed in this document.

Injectors 2A and 2B disclose the ingredients used in the seal formulations. It appears that the anti-infective acriflavin is always present in the formulations shown. Moreover, the generic disclosure of formulation given in the description and the claim does not indicate the possible absence of further anti-infective either.

Therefore, the Board considers that the subject-matter of claim 1 of the request filed during the oral proceedings is not anticipated by the disclosure in document (4) since the claim requires that "no other anti infective" than bismuth subnitrate be present in the seal formulation.

6.2 The respondents' main argument was that acriflavine was not present in the prior art formulations as an anti-infective agent but as a pigment and that the amounts were such that it was even doubtful that it could have any effective anti-infective effect.

The Board cannot follow this argumentation because, as discussed under point 5, the term anti-infective as used in claim 1 does not represent a functional feature, it merely implies that any further compound known as having anti-infective properties cannot be present in the formulation.

Accordingly, the points raised by the respondents, which, if substantiated, might be decisive for the assessment of inventive step, are irrelevant for the assessment of novelty.

Documents (1), (2), (3), (5), (6) and (11) were also cited against the novelty of claim 1.

Since their content is similar to the content of document (4), the argumentation developed under 6.1 applies also to these documents since acriflavin is present in all formulations.

Moreover, document (11) does not disclose a formulation in the form of a gel (see page 295, paragraph 3).

In view of the above, the Board concludes that the subject-matter of claim 1 fulfils the requirements of novelty under Article 54 EPC.

No objections were raised with respect to the remaining claims and the Board sees no reason to differ.

7. *Remittal to the department of first instance*

7.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision which has been issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first instance department issues a decision against a party based solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

7.2 The observations made above apply fully to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of novelty, but disregarded the essential issue of inventive step (Articles 52(1), 56 EPC). This issue, however, formed,

inter alia, the basis for the requests that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

7.3 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar: The Chairman:

N. Maslin U. Oswald