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**Datasheet for the decision
of 8 June 2016**

Case Number: T 0973/13 - 3.3.07

Application Number: 07868403.2

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IPC: A61K33/30, A61K33/24,
A61K33/00, A61P15/14,
A61P31/04, A61K45/06

Language of the proceedings: EN

Title of invention:

INTRA-MAMMARY TEAT SEALANT FORMULATION AND METHOD OF USING SAME
TO REDUCE OR ELIMINATE VISUAL DEFECTS IN AGED CHEESES

Applicant:

Wisconsin Alumni Research Foundation

Relevant legal provisions:

EPC Art. 56, 84, 123(2)

Keyword:

Amendments - allowable (yes)
Claims - clarity after amendment (yes) - support in the
description (yes)
Inventive step - (yes)



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Case Number: T 0973/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 8 June 2016

Appellant: Wisconsin Alumni Research Foundation
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 27 November
2012 refusing European patent application No.
07868403.2 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
P. Schmitz

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division posted on 27 November 2012 refusing European patent application No. 07 868 403.2.
- II. The decision was based on 4 sets of claims filed with letter of 11 September 2012 as main request and auxiliary requests 1 to 3.

Claims 1 and 7 of the main request read as follows:

"1. A composition for use in preventing mastitis in cows by forming a physical barrier in the teat canal of the cow during the cow's dry period and simultaneously preventing black spot defect in dairy products made with milk from the cow, the composition comprising: at least 30% by weight of a bismuth-free, non-toxic compound selected from titanium dioxide, zinc oxide, barium sulfate, or combinations thereof, dispersed in a gel base, wherein the composition has a density sufficient to settle the composition into the teat canal of a cow and thereby forms a physical barrier to entry of microorganisms into the teat canal, and wherein the teat seal formulation does not cause black spot defect in dairy products made with milk from the cow."

"7. An intra-mammary teat sealant for infusion into the teat of a cow for use in preventing mastitis in cows by forming a physical barrier in the teat canal of the cow during the cow's dry period and simultaneously preventing black spot defect in dairy products made with milk from the cow, the teat sealant comprising, in combination: a gel base; and

at least 30% by weight of a compound selected from titanium dioxide, zinc oxide, barium sulfate, or combinations thereof dispersed in the gel base, wherein the composition is devoid of bismuth, has a density sufficient to settle the composition into the teat canal of a cow, and wherein the teat seal formulation does not cause black spot defect in dairy products made with milk from the cow due to the salt being devoid of bismuth."

Auxiliary request 1 included an amended claim 1, in which the quantity of the bismuth-free, non-toxic compound was amended to "at least 50% to 75% by weight", and an amended claim 6, which corresponded to claim 7 of the main request with the amendment made in claim 1 and the deletion of the wording "due to the salt being devoid of bismuth" at the end. Auxiliary request 2 included an amended claim 1, which corresponded to claim 1 of the main request with the specification that the gel base comprises "aluminium stearate or liquid paraffin", and an amended claim 5, which corresponded to claim 7 of the main request with the amendment made in claim 1 and the deletion of the wording "due to the salt being devoid of bismuth" at the end. Auxiliary request 3 included an amended claim 1, which comprised the amendments made to claim 1 in both auxiliary request 1 and auxiliary request 2, and an amended claim 4, which comprised the amendments made to claim 6 of auxiliary request 1 and claim 5 of auxiliary request 2.

III. In the decision under appeal, the following documents were cited *inter alia*:

D1: WO-A-98/26759

D2: WO-A-03/057233

IV. According to the decision under appeal:

- a) Claim 7 of the main request did not meet the requirements of Article 123(2) EPC due to the lack of a basis for the expression "due to the composition being devoid of bismuth" with reference to the feature "the teat seal formulation does not cause black spot defect in dairy products made with milk from the cow".
- b) The subject-matter of claim 1 of the main request was novel over the cited prior art, but it was not inventive over document D2, taken as the closest prior art, from which it differed in that the composition was formulated as a gel. As there was no technical effect related to this difference, the problem was the provision of an alternative composition for use in preventing/treating mastitis and improving the quality of milk and the solution was not inventive, as the use of a gel base with high amounts of heavy metals was known from D1. The same objection held for independent claim 7.
- c) The main request did not meet the requirements of Article 84 EPC in view of several expressions defining results to be achieved and the expression "gel base" which was very broad and not fully supported.
- d) The same objections under Articles 56 and 84 were valid for the independent claims of auxiliary requests 1 to 3.

V. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of

appeal, the appellant submitted two sets of claims as auxiliary requests 4 and 5.

- VI. In a communication sent in preparation of oral proceedings, the Board emphasised *inter alia* some issues related to compliance with the requirements of Article 84 EPC and objected to the presence of two independent claims in the same category under Rule 43(2) EPC (points 2.1 to 2.3).
- VII. With letter of 29 April 2016, the appellant withdrew the previous requests and filed six sets of claims as main request and auxiliary requests 1 to 5.
- VIII. After a telephone conversation with the rapporteur on 25 May 2016, the appellant filed with letter of 1 June 2016 a single set of claims as main request.

Claim 1 of the main request read as follows:

"1. A composition for use in preventing mastitis in cows by forming a physical barrier in the teat canal of the cow during the cow's dry period and simultaneously preventing black spot defect in dairy products made with milk from the cow, the composition comprising:
at least 30% by weight of a bismuth-free, non-toxic compound selected from titanium dioxide, zinc oxide, barium sulfate, or combinations thereof, dispersed in a gel base."

The request did not include any other independent claim.

- IX. The appellant's arguments, insofar as relevant to the present decision, can be summarised as follows:

Article 84 EPC

- a) The feature "gel base" did not result in a lack of clarity or of support, as the skilled person knew whether he was working inside or outside the scope of the claims and as it was well recognised that something broad could be supported by something more limited.

Inventive step

- b) Document D2 could not be considered as the closest prior art, as it disclosed compositions to be administered orally or through injections of the active in a low viscosity carrier by means of a syringe, while it was silent with respect to the administration to the teat in the form of an intra-mammary teat seal. In view of this, no further comment on the argumentation of the examining division was necessary. The composition of claim 1 differed from the compositions disclosed in document D1, which, being directed to intra-mammary teat seals in the form of gels, was the closest prior art, in that it was devoid of bismuth and contained at least 30% by weight of a bismuth-free, non-toxic compound selected from titanium dioxide, zinc oxide, barium sulfate, or combinations thereof dispersed in the gel base. As by means of these features an intra-mammary teat seal was obtained which was suitable to prevent mastitis, but did not give rise to black spot defect, the problem was the provision of an improved intra-mammary teat seal and the solution was not obvious, as it was not recognised in the prior art that the bismuth salt was the cause of black spot defects.

- X. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the set of claims filed as main request with letter of 1 June 2016.

Reasons for the Decision

Article 123(2) EPC

1. The only objection under Article 123(2) EPC in the decision under appeal concerned the presence of the wording "due to the composition being devoid of bismuth" with reference to the feature "the teat seal formulation does not cause black spot defect in dairy products made with milk from the cow" in claim 7 of the main request on which the decision was based.
 - 1.1 The claims of the main request on which it is to be decided upon do not contain the objected wording, nor the feature to which this wording referred. The objection is therefore rendered moot by the amendments filed in appeal.
 - 1.2 The Board sees no reason to discuss any other issue under Article 123(2) EPC.

Article 84 EPC

2. The claims of the main request on which the decision was based were considered not to comply with the requirements of Article 84 EPC in view of the presence of two features defining results to be achieved ("wherein the composition has a density sufficient to settle the composition into the teat canal of a cow and

thereby forms a physical barrier to entry of microorganisms into the teat canal" and "wherein the teat seal formulation does not cause black spot defect in diary products made with milk from the cow") and of the feature "dispersed in a gel base" which was considered broader than justified and therefore lacking support. The same objections were raised against the claims of the auxiliary requests.

- 2.1 The claims of the main request on which it is to be decided upon do not contain the features defining results to be achieved, which were objected to. The objection is therefore rendered moot by the amendments filed in appeal.
- 2.2 As to the feature "dispersed in a gel base", the Board does not see any reason to consider it as unclear or as lacking support. The application mentions that any gel "known in the pharmaceutical arts" can be suitable for the claimed composition (page 4, lines 3-4 of the original application). While it is true that some gels are disclosed as "preferred" or "typical" (page 4, lines 4-6 and 13-14), there is no reason why the composition should be limited to them, as the skilled person would imagine that any other gel suitable for pharmaceutical application should equally work. In addition, the term "gel" leaves no doubt to the skilled person about what is covered and what is not.
- 2.3 For these reasons, the requirements of Article 84 EPC are considered to be met.

Inventive step

3. The main disputed point about the decision under appeal concerns the choice of the closest prior art, namely

whether it is represented by D1 as according to the appellant or by D2 as in the decision.

- 3.1 Document D1 discloses a seal formulation to provide an anti infective-free physical barrier in the teat canal (claim 1) for the prophylactic treatment of mastitis in cows (page 1, first sentence) to be administered during the cow's dry period (page 1, last paragraph). The composition preferably comprises 50% to 75% by weight of a non-toxic heavy metal salt in a gel base (page 2, lines 22-26), wherein the salt is preferably bismuth sub-nitrate (page 2, lines 28-29). No other salt is mentioned.
- 3.2 Document D2 discloses a composition for preventing or treating mastitis comprising chitosan-chitooligo-saccharide and bromelain as active ingredients (claim 1), which may comprise 0.5 to 30% of a zinc compound, which may be zinc oxide (page 3, lines 21-26). The formulation may be administered orally or by injection; in case of administration by injection the carrier is water, ethyloleinate, ethanol, propylene glycol or glycerine (paragraph bridging pages 4 and 5).
- 3.3 While the compositions of D1 are teat seals as the ones of the application under analysis, those of D2 are not suitable for such a mode of administration, as they are either for oral administration or prepared in a liquid carrier which cannot form a seal. Moreover, teat seals are not mentioned in D2.
- 3.4 Out of these two documents, it is therefore clearly D1 which constitutes the closest prior art, as, contrary to D2, it discloses a composition suitable for the intended purpose and mode of administration.

- 3.5 The composition of claim 1 differs from the compositions of D1 in that it contains at least 30% by weight of a bismuth-free, non-toxic compound selected from titanium dioxide, zinc oxide, barium sulfate, or combinations thereof and, being devoid of bismuth, is devoid of the preferred (and the only disclosed) salt of D1 (bismuth sub-nitrate).
- 3.6 The studies in the application (pages 5 to 10) clearly show that it is the presence of the bismuth salt in the teat seal that is responsible of the presence of black spots in cheese produced by milk of cows whose teats have been sealed by teat seals containing bismuth salts. It is therefore clear that by eliminating the bismuth salts from the teat seal the black spot defect can be eliminated. The examples in the application (pages 10 to 14) show that by eliminating the bismuth salt and replacing it with other metal compounds, teat seals are obtained which are retained within the teats of non-lactating cows as well as the ones with bismuth sub-nitrate. This means that an improvement with respect to the teat seals of D1 can be acknowledged (the elimination of black spot defects). As the effect is explicitly cited in claim 1 ("simultaneously preventing black spot defect in dairy products made with milk from the cow") this also constitutes a further difference between the teat seal of claim 1 and the ones of D1.
- 3.7 On this basis, the technical problem solved with respect to D1 is the provision of improved teat seals.
- 3.8 As mentioned above, D1 does not disclose any salt other than bismuth sub-nitrate. D2 mentions zinc oxide, however without mentioning any possible advantages of its use and in the context of very different compositions, which are not teat seals. In addition none

of the available documents addresses the issue of black spot defects.

- 3.9 Therefore, it can be concluded that no hints can be found in the available prior art that a salt not containing bismuth should be used in the teat seals of D1 in order to obtain an improved teat seal.
- 3.10 For these reasons, the teat seal of claim 1 of the main request involves an inventive step starting from D1 as the closest prior art.
- 3.11 No different conclusion can be reached, if starting (although artificially, see points 3.3 and 3.4) from D2 as the closest prior art. Even accepting the analysis of the examining division up to the formulation of the technical problem as the provision of an alternative composition, the skilled person would not combine two documents (D2 and D1), which both relate to the prophylactic treatment of mastitis, but concern completely different types of compositions, the former being an antibiotic and anti-inflammatory composition to be administered orally or by injection and the latter being an antiinfective-free teat seal. In view of these fundamental differences, the skilled person would have no reason to combine ingredients and structure of the two compositions without hindsight.
- 3.12 For these reasons, the main request meets the requirements of Article 56 EPC.

Conclusion

4. As none of the objections on which the refusal was based holds for the claims of the main request and the Board sees no reason to raise any other objection, the case is

to be remitted for grant on the basis of these claims and a description to be adapted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent on the basis of the set of claims filed as main request with letter of 1 June 2016 and a description to be adapted.

The Registrar:

The Chairman:



K. Boelicke

J. Riolo

Decision electronically authenticated