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Datasheet for the decision of 21 November 2013

Case Number: T 1133/09 - 3.3.07

Application Number: 97949079.4

Publication Number: 971690

IPC: A61K9/00

Language of the proceedings: EN

Title of invention:
ANTIINFECTIVE FREE INTRAMAMMARY VETERINARY COMPOSITION

Patent Proprietor:
BIMEDA RESEARCH & DEVELOPMENT LIMITED

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

Relevant legal provisions:
EPC Art. 56, 111(2)
RPBA Art. 13, 12

Keyword:
Late-filed documents
Inventive step - non-obvious alternative

Decisions cited:
T 0028/06

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Case Number: T 1133/09 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 November 2013

Appellant: (Patent Proprietor)	BIMEDA RESEARCH & DEVELOPMENT LIMITED Broomhill Road, Tallaght, Dublin 24 (IE)
Representative:	O'Brien, John Augustine John A. O'Brien & Associates Third Floor, Duncairn House, 14 Carysfort Avenue Blackrock, Co Dublin (IE)
Respondent 1: (Opponent 1)	VIRBAC S.A. BP 27 06511 CARROS Cedex (FR)
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Respondent 2: (Opponent 2)	Akzo Nobel N.V. P.O. Box 9300 NL-6800 SB Arnhem (NL)
Representative:	Mestrom, Joannes Jozef Louis Intervet International B.V. Patent Department P.O. Box 31 5830 AA Boxmeer (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 March 2009 revoking European patent No. 971690 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

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 10 March 2009 to revoke European Patent 0 971 690.

II. Two notices of opposition were filed against the granted patent requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step, insufficiency of disclosure and extension of the subject-matter beyond the content of the application as filed in accordance with Article 100(a), (b) and (c) EPC.

III. The patent was firstly revoked by the opposition division for lack of novelty.

IV. In appeal proceedings following that decision, Board of Appeal 3.3.02 decided in T 0028/06 of 21 March 2007 to remit the case to the opposition division for further prosecution. The decision was based on the claims of the main request filed during oral proceedings on 21 March 2007. Independent claims 1 and 7 of that request read as follows:

"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."

V. In T 0028/06 it was decided that the claims of the main request met the requirements of Articles 84 and 123 EPC, that the grounds of opposition under Article 100(b) EPC did not prejudice maintenance of the patent and that the requirement of novelty was met. In particular the subject-matter of claim 1 was novel with respect to document D4 (GB-A-2 273 441). In this respect the Board stated that "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", "the anti-infective acriflavin is always present in the formulations shown" (in D4) and "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" (point 6.1 in the grounds of the decision, last three paragraphs on page 14).

VI. The subsequent decision of the opposition division was based on the set of claims on which the Board's decision was based.

VII. In the course of the proceedings leading to the appealed decision the following documents were cited *inter alia* in addition to D4:

D1: IE 930947
D2: WO-A-94/13261
D3: WO-A-95/31180
D5: GB-A-2 273 443
D6: GB-A-2 273 655
D7: GB-A-1 441 747
D11: W.J. Meaney "Effect of a dry period teat seal on bovine udder infection", Irish Journal of agricultural Research, 1977, volume 16, pages 293 to 299
D23: RU-C-2 028 798 and English translation thereof
D34: M.W. Woolford et al., "The prophylactic effect of a teat sealer on bovine mastitis during the dry period and the following lactation", New Zealand Veterinary Journal, 1998, volume 46, pages 12 to 19
D40: "Mastitis: Verloor jy nog onwetend geld?", PRO Agri, September 1996, pages 5 to 9
D41: translation of D40 into English
D42: "Dorland's Illustrated Medical Dictionary", W.B. Saunders Company, 1994, page 19
D44: "Baillière's Comprehensive Veterinary Dictionary", Baillière Tindall, 1988, page 11
D45: G.G. Tawil et al. "Bacteriostatic and Bactericidal Activities of Acriflavine-Antibiotic Combinations", Scientia Pharmaceutica, 1986, volume 54, pages 19 to 22

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

a) The subject-matter of claim 1 of the main request differed from the disclosure of D4, which was the closest prior art, by the requirement for the formulation to be free of anti-infective, other than bismuth sub-nitrate.

b) The problem solved over D4 was the provision of a mere alternative which was also effective against

mastitis to a certain extent, as the patent on its own or in combination with documents D11 or D34 did not show that the omission of acriflavine from the teat seal compositions disclosed in D4 led to an unexpected effect. In particular the contested patent as well as D34 demonstrated that using a teat seal formulation free of anti-infective other than bismuth subnitrate was effective in preventing mastitis to the same extent as a formulation comprising an antibiotic and in D11 it was demonstrated that a teat seal with acriflavine was as effective as a teat seal with antibiotics and acriflavine. In view of that, the available evidence could not demonstrate that a teat seal without acriflavine was as effective as a teat seal with acriflavine.

c) Leaving out acriflavine from the compositions of D4 was an arbitrary and obvious modification of the formulations disclosed therein in order to provide a mere alternative, as there was no sufficient evidence to confirm a technical prejudice that in any dry cow treatment antibiotics and anti-infectives (such as acriflavine) were to be used and acriflavine was not indicated as an essential compound in D4, but only as a pigment without stressing its importance for achieving a better or simply a necessary prophylactic effect. While it might well be that a more hygienic environment was necessary or that the prevention rate was not exactly the same compared to the use of seal formulations comprising in addition the antiseptic colour acriflavine, in view of the lacking experimental evidence and the consequently underlying technical problem of providing a mere alternative, this was

not of relevance. Prior art such as D23, where mastitis was prevented by the use of a mere teat seal formulation in absence of any antibiotic or anti-infective, confirmed the expectation of the skilled person that a prophylactic effect against mastitis could be achieved by a purely physical blocking of the teat canal in the absence of any antibacterial agent.

d) Therefore the subject-matter of claim 1 of the main request did not involve an inventive step. The same argumentation applied to the process for preparing a seal formulation of claim 7.

IX. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant filed three sets of claims as main request and auxiliary requests 1 and 2 and submitted two new documents:

D47: A.W. Stableforth et al. "Entozon and Acriflavine for the Treatment of Chronic, Contagious Bovine Mastitis", The Veterinary Record, 1938, volume 50, pages 663 to 676
D48: S.D. Johnson "Observations on the treatment of mastitis with acriflavine", Cornell Vet. 1941, volume 31, pages 127 to 148

In the statement of grounds it was announced that a series of experiments had been commissioned to provide a comparison with the treatment disclosed in document D4, which would be filed as soon as completed.

X. In their replies to the statement setting out the grounds of appeal opponent 1 and 2 (respondent 1 and 2) maintained the objection of lack of inventive step. In

the reply of respondent 2 to the grounds a further document was submitted:

D49: G. Sykes "Disinfection and sterilisation", E. & F. N. Spon LTD, 1965, pages 352 to 360

XI. Subsequently to the statement of grounds and the reply thereto the parties submitted the following additional pieces of evidence:

with letter of respondent 2 dated 6 January 2010
D50: EP-A-0 076 068,

with letter of the appellant dated 17 February 2010:
D51: Report on field trial to compare the efficacy of Teat Seal and Teat Seal containing 0.1% Acriflavine after Experimental Challenge with *Streptococcus dysgalactiae* in Nonlactating Dairy Cows
D52: Witness Statement of Paul D. Brady dated 16 February 2010
D53: Witness Statement of Robert Draper dated 16 February 2010 including exhibit RD1 and RD2,

with letter of the appellant dated 26 March 2010:
D54: Curriculum Vitae of W.J. Meaney
D54': First declaration of W.J. Meaney dated 25 March 2010,

with letter of respondent 1 dated 13 February 2012:
D55: Statutory rules 1995 No. 27, Agricultural and Veterinary Chemicals Code Regulations
D56: Residue Guideline No. 25, Residue in milk - Antimicrobials, Commonwealth of Australia Gazette, No. NRA 2, 1 February 2000
D57: Reglement (CEE) n° 2377/90 du Conseil du 26 juin 1990, Journal Officiel n° L 224 du 18.8.1990

D58: "The Intramammary Therapy of Bovine Mastitis", Journal of the American Veterinary Medical Association, Vol. CVIII, No. 828, March 1946, pages 127 to 135
D59: Declaration of Georges Bufala dated 3 February 2012
D60: Curriculum Vitae of Georges Bufala,

with letter of the appellant dated 28 September 2012:
D61: Second declaration of W.J. Meaney dated 28 September 2012,

with letter of the appellant dated 21 October 2013:
D62: First declaration of Mathys Gerhardus Snyman dated 21 October 2013 including Annex 1 and Annex 2

XII. Oral proceedings were held on 21 November 2013. During the oral proceedings the appellant submitted former auxiliary request 1 as new main request and withdrew all other requests. The new main request contained six claims which were identical to claims 1 to 6 of the main request filed during oral proceedings before the Board of Appeal in first appeal proceedings on 21 March 2007, claims 7 to 15 (process claims) of the former main request being deleted. It contained a single independent claim, namely use claim 1.

XIII. The arguments of the appellant can be summarised as follows:

Evidence filed in appeal

a) Both the filing of documents D47 and D48 and the filing of the pieces of evidence D51 to D53 were a reaction to the decision under appeal and related to its key issues. D47 and D48 were filed with the statement of grounds and supported the long

standing prejudice that a dry cow treatment of mastitis would not be carried out without anti-infective substances and in particular acriflavine, which prejudice was not acknowledged in the decision. D51 to D53 related to new tests which were announced in the statement of grounds, but filed only later, as time was needed to get the appropriate licences and accomplish the tests. They showed that the technical problem of providing a composition as effective as the one of D4, which had not been acknowledged in the decision, had effectively been solved. These pieces of evidence had to be admitted into the proceedings on that basis, as was the case also for D54', which was a reaction to a point raised by one of the respondents, D61, which was also a reaction to a new allegation, and D62, which was a clarification by the author of D40. Document D50 was not relevant, as it related to a teat seal based on a silicone polymer, and should therefore not be admitted.

Inventive step

b) Starting from document D4 as the closest state of the art and from the analysis thereof in T 0028/06, which identified the difference in the requirement of granted claim 1 that no other anti-infective than bismuth subnitrate be present in the seal formulation, the presence of an inventive step could be acknowledged by recognising two errors in the analysis in the appealed decision, the first one being in the formulation of the technical problem and the second in ignoring a technical prejudice present in the art.

c) The new experiments filed in appeal with D51 showed without doubt that the use of a formulation without acriflavine according to granted claim 1 was as effective as the one of D4. These tests were statistically sound and the comparative experiments therein were done using a quantity of acriflavine of 0.1% by weight which was the one used in D4 and a usual quantity in the art for an anti-infective as confirmed by several documents (e.g. D44, D45, D47 and D48). The problem solved was therefore the provision of an alternative formulation which was equally effective or even of an improved formulation, since no side effect related to the use of a medicament were present.

d) It was common general knowledge in the field that a teat seal formulation did not work only as a physical plug, but had always also an anti-infective function. The fact that this function was normally accomplished by acriflavine also belonged to the common general knowledge. Documents D47 and D48 were old documents which showed that the anti-bacterial properties of acriflavine in compositions for treating bovine mastitis had been known for a long time in the pre-antibiotics era. When antibiotics were introduced, still acriflavine was used as anti-infective. When later seals began to be used to avoid mastitis, still they always had to contain acriflavine as anti-infective, as confirmed by several documents (D1 to D3, D5, D6, D7, D11). These documents confirmed the consistent teaching that pathogens might be introduced with the seal and that therefore the presence of an anti-infective substance was necessary. On that basis

the skilled person reading D4 would understand that acriflavine was used in the formulation with an anti-infective function without the need to mention it. The coloring function, which was indicated in D4, was as such not relevant, as the skilled person, if interested only in that function, would have chosen a compound without pharmacological properties.

e) On that basis the skilled person looking for an equally effective formulation would not expect that it could be obtained by removing acriflavine. In this respect it was important that a key point in T 0028/06 was that acriflavine was an essential ingredient in the formulations disclosed in D4. Even documents D23 and D40 could not lead the skilled person to a different conclusion. D23 related to a very different formulation, used heat to disinfect and obtained bad or at least not clear results, so that its teaching was not sufficient to make the skilled person abandon the consistent teaching to use acriflavine. D40 did not disclose a complete formulation, so that it also could not point to the elimination of an ingredient which was consistently considered as essential. On that basis, the skilled person trying to solve the problem posed would not remove acriflavine from the formulation used in D4. The subject-matter of granted claim 1 was therefore inventive.

XIV. The arguments of the respondents can be summarised as follows:

Evidence filed in appeal

a) The documents filed by the appellant with the statement of grounds were late filed. D47 and D48 were very old documents which did not address the relevant questions regarding acriflavine and were filed eight years after the discussion about the role of acriflavine had started. Also the experimental report in D51 to D53 related to the role of acriflavine and was filed 10 years after the beginning of the opposition procedure and eight years after the start of the discussion about the role of acriflavine. On that basis these pieces of evidence should not be admitted into the proceedings. The declarations of some experts, which were filed even later, were not relevant and should not be admitted.

Inventive step

b) Document D4, as closest state of the art, disclosed a treatment, which according to decision T 0028/06 differed from the one of granted claim 1 in the requirement that no other anti-infective than bismuth subnitrate be present in the seal formulation. While it was not contested that the problem was the provision of an equally effective formulation with teat sealing properties, the simple removal of acriflavine could not be seen as an inventive solution to the problem posed.

c) No prejudice against the removal of acriflavine was present in the art. Documents D47 and D48 dating back several decades related to the treatment of infections in the old days and could not support the existence of a prejudice.

Documents D1, D2, D3, D5 and D6 had roughly the same content and none of them included the teaching that an anti-infective substance was needed in the formulations disclosed therein. In D7 it was clear that penicillin was the essential ingredient and not acriflavine. D4 and D11 related to the elimination of antibiotics from teat seal formulations and in spite of the presence of acriflavine did not mention any anti-infective function. In particular D4 referred to acriflavine always as a pigment used therefore to distinguish the formulation from others, which was confirmed by the use of a quantity of the compound which was too small to be effective as anti-infective. Decision T 0028/07 confirmed that acriflavine was always present in the compositions of D4, but that there was no suggestion therein about an anti-infective function. On that basis the skilled person would have no difficulty to leave out a non essential component. On the contrary he would expect that by taking out the pigment the effectiveness of the formulation would remain the same, as confirmed by the tests in D51, which did not show any improvement. He would actually do so with the desire to simplify the formulation by eliminating a non essential component.

d) Even accepting that some old documents supported the presence of a prejudice, its existence would be cleared out by the teaching of more recent publications. Document D4 itself explained the features of an ideal seal without mentioning the need of an anti-infective. D23 showed a seal formulation without anti-infective ingredients which gave good results under challenging conditions; in applying the seal disclosed

therein, it could not be considered that the anti-infective function could be achieved through heating, as application at high temperature would be too painful for the treated cows. Also in the seal of D40 no acriflavine was present. As a single document was enough to take away a prejudice and several pieces of evidence were available against the claimed prejudice, it was clear that, even if it were there in the past, it did not exist any longer at the relevant point in time. On that basis the removal of acriflavine from the formulation of D4 was an obvious measure for the skilled person looking for equally effective formulations and the subject-matter of granted claim 1 did not involve an inventive step.

XV. The appellant requested that the decision under appeal be set aside and the patent be maintained based on the main request filed during the oral proceedings before the Board.

XVI. The respondents requested that the appeal be dismissed and the patent be revoked.

Reasons for the Decision

Evidence filed in appeal

1. The parties to the proceedings filed a large number of documents in appeal, namely documents D47 to D62. It is up to the Board to decide which of these pieces of evidence are admitted into the proceedings.

1.1 Documents D47 and D48 were filed by the appellant with the statement of grounds to address a key issue of the decision, namely the lack of sufficient evidence for a

technical prejudice that in any dry cow treatment anti-infective substances, such as acriflavine, were to be used. These old documents show that acriflavine had been used as an anti-infective for the treatment of mastitis long before the filing of the patent in suit. On that basis they can be seen as a reaction to the decision under appeal and appear to be *prima facie* relevant, so that the Board finds it appropriate to exercise its discretion by admitting these documents into the proceedings.

1.2 A similar situation is present for document D51 which contains experimental evidence which was announced in the statement of grounds and was filed as soon as available in view of the technical difficulties and the time needed to run the experiments. This document addresses a second key issue of the decision under appeal, namely the lack of sufficient evidence for allowing a comparison between the formulation according to document D4 and a formulation without acriflavine according to claim 1 of the main request, as the evidence available in opposition proceedings was not considered sufficient in this respect. D51 can be seen as a rection to the decision and appears to be *prima facie* relevant, as it clearly provides the missing evidence. The same holds for documents D52 and D53, which complement the information in D51, as far as the running of the experiments is concerned. On that basis the Board finds it appropriate to exercise its discretion by admitting documents D51, D52 and D53 into the proceedings.

1.3 Document D49 was the only documents filed by one of the respondents (respondent 2) with their replies to the statement of grounds. However, it is hardly referred to in the letter of reply of respondent 2 (see page 2 of

that letter, seventh paragraph, first two lines) and it refers to a side aspect (whether acriflavine may be irritant) of the analysis of inventive step, which has no role in this analysis. On that basis the Board finds it appropriate to exercise its discretion by not admitting document D49 into the proceedings.

1.4 All remaining documents filed in appeal have not been filed with the statement of grounds and the reply thereto, which according to Article 12(2) of the Rules of Procedure of the Boards of Appeal (RPBA) should contain a party's complete case. As the central points in the discussion of inventive step, which is the only issue under analysis in the decision under appeal and in the present decision, namely the formulation of the problem solved and the obviousness of the removal of acriflavine from the formulation of D4 in view of the evidence available, have not changed in appeal and no justification has been provided by the parties for the late submission of these further documents, the Board finds it appropriate to exercise its discretion by not admitting these documents into the proceedings (Article 13(1) RPBA. This applies to documents D50 and D54 to D62 (see point XI, above).

Inventive step

2. *Closest prior art*

2.1 There was agreement among the parties on the choice of document D4 as the closest prior art. The Board sees no reason to take a different view on the issue.

2.2 The analysis of document D4 with respect to claim 1 of the main request, including the identification of the features of the claim disclosed therein and of the

distinguishing feature, is part of the *ratio decidendi* of decision T 0028/06 (see point V, above) and is binding for the present decision, as was binding for the decision under appeal (Article 111(2) EPC).

2.3 In T 0028/06 the Board decided that the subject-matter of claim 1 of the main request (claim 1 of the request analysed by the Board therein is identical to claim 1 of the main request) "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" (last paragraph of point 6.1 in the reasons of the decision), while it "appears that the anti-infective acriflavin is always present in the formulations shown" (last but one paragraph in point 6.1).

3. *Problem solved*

3.1 According to the patent in suit, its object is "providing an improved veterinary composition, particularly for the prophylactic treatment of mastitis in dry cows" (paragraph [0006] in the patent). The question therefore arises about the effectiveness of the formulation according of claim 1 with respect to the formulation of D4 in the prophylactic treatment of mastitis.

3.2 The experiments contained in D51 are meant to compare the effectiveness of a seal formulation according to claim 1 in the prophylactic treatment of mastitis with the effectiveness of a seal formulation according to document D4.

3.2.1 Two types of teat seal materials were compared differing only in the presence of 0.1% acriflavine in

the comparative material (D51, page 2, last paragraph of section "Materials and Methods"). The production of the teat seals is described in document D53, which makes reference to exhibit RD2 for the manufacture of a teat seal containing Alugel DF, liquid paraffin, bismuth subnitrate and acriflavine according to D4 (see page 12 of D4 and the Batch Card for Teat Seal 65% w/w Red Trial in exhibit RD2) and of a teat seal according to the patent which differs therefrom only in the absence of acriflavine (see the Batch Card for Teat Seal 65% w/w Blue Trial in exhibit RD2).

3.2.2 The trials involved 52 quarters in 13 uninfected cows selected at drying off, whereby two quarters in each cow were infused with the acriflavine free teat seal formulation and two quarters with the formulation containing acriflavine (D51, page 2, section "Materials and Methods"). All of the sealed quarters were then inoculated with a culture of *Streptococcus dysgalactiae*, deposited into the teat sinus (D51, pages 2 and 3, sections "Challenge Culture" and "Inoculation Procedure").

3.2.3 The cows were thereafter observed daily for signs of clinical mastitis and the new clinical cases were identified and sampled (D51, page 3 and 4, sections "Clinical Examination of Udder Quarters" and "Results"). The results were analysed statistically and it was found that there was no significant difference between treatment groups (D51, page 4, section "Statistical Analysis"), so that the conclusion was drawn that despite the absence of the anti-infective material acriflavine from the test teat seal formulation, its performance in dairy cows was equivalent to the performance of the control teat seal

containing 0.1% acriflavine (D51, page 6, section "Conclusions").

3.3 The tests in D51 provide the appropriate comparison between a treatment with compositions according to D4 and according to the patent and permit to conclude that there was no loss in effectiveness in the prophylactic treatment of mastitis by the removal of acriflavine from the composition. In view of that there is no need to analyse the further experimental evidence on file.

3.4 The problem solved by the subject-matter of claim 1 of the main request with respect to D4 is therefore the provision of a simplified seal formulation for the preparation of a medicament for prophylactic controlling mastitis which is as effective as the one of D4.

4. *Obviousness*

4.1 The key issue on which most of the disagreement among the parties was expressed regarded the analysis of obviousness, namely the analysis of the question whether the removal of acriflavine from the formulation of D4 is an obvious solution to the posed problem.

4.2 In this respect it is relevant to analyse the knowledge of the skilled person with regard to the role of acriflavine in compositions as the one disclosed in D4.

4.2.1 Acriflavine is a well known antiseptic as confirmed by documents D42 (page 19, see definition of acriflavine as "a mixture used in solution as a topical antiseptic for the skin and mucous membranes") and D44 (page 11, see definition of acriflavine as "an antiseptic dye

used for topical application"), which are extracts from a medical and veterinary dictionary respectively.

4.2.2 Its use in the prophylactic and therapeutic treatment of mastitis has been known for a long time, as confirmed by documents D47 (see title and page 675, section "Summary", subsection "Acriflavine" and section "Conclusion") and D48 (see title and page 147-148, section "Summary"). Its bactericidal activity was also known in combination with antibiotics (see D45, title and section "Results and Discussion" on pages 20 to 22).

4.3 On that basis it must be acknowledged that acriflavine has a clear role in a formulation for the treatment of mastitis as the one of D4, namely it is there as an anti-infective, regardless of whether this function is mentioned in the document itself, as this is well known by any practitioner working in the field.

4.3.1 The fact that acriflavine is indicated as a pigment in D4 does not make any difference in this respect and constitutes only additional information on a further property of the compound.

4.3.2 As to the quantity of acriflavine in the formulation of D4 (0.1%), it corresponds to (or is even higher than) the ones indicated in the documents which mention its antiseptic and anti-infective function (D44, page 11, second line in the definition of acriflavine; D45, table III on page 21; D47, page 675, section "Summary", subsection "Acriflavine"; D48, page 147-148, section "Summary") and it reinforces therefore the fact that a skilled person would understand, by reading D4, that acriflavine is there as an anti-infective.

4.4 In addition, acriflavine is always present in all the teat seal formulations of the prior art based on heavy metal salts, namely in addition to those of D4 the ones of documents D1 (table on page 7 and tables on the bottom of pages 9, 10 and 11, see similarly documents D3 and D5) and D2 (tables on pages 9, 11, 12, 13, 15, 18, 19 and 20, see similarly document D6), which are quite similar to those of D4, and also the ones of documents D7 (see example on page 2) and D11 (see page 295, "Composition of seal" including note 3 at the bottom of the page). Even though in these documents the anti-infective function is not explicitly mentioned, the presence of acriflavine as anti-infective directly derives from the common general knowledge of the skilled person (see points 4.2.1 and 4.2.2, above).

4.5 On that basis, even though acriflavine is not presented explicitly as an essential ingredient in the formulations of D4, which focuses on other aspects of the compositions disclosed therein, it is clearly a necessary ingredient of these compositions, as confirmed by the fact that acriflavine is always present in the formulations shown therein (as indicated already in T 0028/06, see last but one paragraph of point 6.1 in the reasons of the decision).

4.6 In view of that, the skilled person would not remove acriflavine from the formulations of D4 in order to solve the problem posed as, due to the constant use of acriflavine as anti-infective in the formulations of the prior art, he could not expect that, in spite of the removal, the effectiveness of the formulation would be maintained.

4.7 This conclusion cannot be changed by the further documents cited by the respondents in this respect, namely D23, D40 and D4 itself.

4.7.1 Document D23 relates to a method for preventing mastitis in cows by introducing molten paraffin as a prophylactic means into each healthy teat of an udder on day 11-12 after ceasing to milk (claim 1). It was found that paraffin has an analgesic and antispastic effect, accelerates the resorption of haematomas, as well as the processes of regeneration and tissue metabolism and is capable of emitting heat for a fairly long time when solidifying (page 3, lines 15 to 22 of D41). It was also found that use of the method ensures reduction in the affection of cow udders with mastitis via the teat canal in the post-calving period and reduction in expenditure on the acquisition of a preparation capable of preventing mastitis (page 3, lines 23 to 28 of D41).

4.7.2 D23 relates therefore to a teat seal quite different form the one used in claim 1 of the main request (molten paraffin instead of a gel base comprising bismuth subnitrate), makes use of heat which potentially has an antiseptic effect and does not give any indication that the presence or absence of an anti-infective substance in a teat seal formulation does not affect its effectiveness. It cannot provide any hint therefore to the skilled person at removing acriflavine from the formulation of D4 in order to solve the problem posed.

4.7.3 Document D40 illustrates a teat seal on the market called Cloxamast which is composed of a double dosage in which the first injector (Teat Seal 1) contains the antibiotic Cloxacillin, while the second injector (Teat

Seal 2) mostly contains bismuth subnitrate (see D41, the translation into English of D40, page 3, section "The new concept: double protection"). A full composition for Teat Seal 2 is however not indicated in the document, so that it cannot be derived therefrom that Teat Seal 2 does not contain acriflavine, nor that the document would suggest the removal of acriflavine from similar compositions.

4.7.4 The fact that document D4 itself does not make any reference to the anti-infective function of acriflavine, not even in the sections where the characteristics of an ideal teat seal are listed (page 7, line 17 to page 8, line 4; page 13, line 23 to page 14, line 7) can also not be taken as an indication that acriflavine could be removed without changing the effectiveness of the composition, as the anti-infective function is implicit to the person skilled in the art reading D4, as explained above (see points 4.2 and 4.3).

4.8 For these reasons it is concluded that the subject-matter of claim 1 of the main request involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the claims of the main request filed during the oral proceedings before the Board and a description to be adapted thereto.

The Registrar: The Chairman:

L. Fernández Gómez J. Riolo

Decision electronically authenticated