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Datasheet for the decision of 22 August 2017

Case Number: T 0671/12 - 3.3.01

Application Number: 06700797.1

Publication Number: 1838295

IPC: A61K31/00

Language of the proceedings: EN

Title of invention:
ANTHELMINTIC COMPOSITION

Patent Proprietor:
NORBROOK LABORATORIES LIMITED

Opponent:
Merial Limited

Headword:
Anthelmintic formulation/NORBROOK

Relevant legal provisions:
EPC Art. 87(1), 56, 113(1), 116(1)
RPBA Art. 12(3), 12(4)

Keyword:
Inventive step - (no) arbitrary selection

Decisions cited:
T 0003/90, T 0663/10, T 0910/02

Catchword:

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Case Number: T 0671/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 22 August 2017

Appellant: (Patent Proprietor)	NORBROOK LABORATORIES LIMITED Station Works Newry, County Down BT35 6JP (GB)
Representative:	HGF Limited 8th Floor 140 London Wall London EC2Y 5DN (GB)
Appellant: (Opponent)	Merial Limited 3239 Satellite Blvd Duluth, GA 30096-4640 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 27 January 2012 concerning maintenance of the European Patent No. 1838295 in amended form.**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	L. Bühler

Summary of Facts and Submissions

I. The present appeals by the patent proprietor (appellant patentee) and the opponent (appellant opponent) lie from the interlocutory decision of the opposition division concerning maintenance of the European patent No. 1 838 295 in amended form.

II. Claim 1 of the patent as granted read as follows:

"1. A topical anthelmintic formulation comprising as active ingredients, a therapeutically effective amount of at least one anthelmintic agent derived from *Streptomyces avermitilis*, with a therapeutically effective amount of at least one other anthelmintic of the sulphonamide type, in an alcoholic solvent-based carrier suitable for topical administration and delivery of the active ingredients transdermally, said carrier comprising at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100% and optionally excipients and formulation aids."

Claim 1 of the **request held allowable by the opposition division** differed from claim 1 of the patent as granted in the specification that the anthelmintic agent derived from *Streptomyces avermitilis* is an avermectin and the anthelmintic sulphonamide is clorsulon.

III. The evidence invoked by the parties during the opposition/appeal proceedings included *inter alia* the following prior art documents and experimental reports, documents (2), (3), (9), (10), (12), (14) to (17) and (20) having already been cited in the opposition proceedings:

(2) WO 02/09764

(3) WO 97/26895

(9) US 3980791

(10) US 4336262

(12) WO 2004/089239

(14) WO 01/60380

(15) Environmental Impact Analysis Report, Clorsulon (Merck Sharp & Dohme Reseach Laboratories) 10 January 1985

(16) Material Safety Data Sheet (Ivomec Pour-On For Cattle) 16 March 2004

(17) WO 00/30449

(20) WO 2005/007241

(27) David W. Fink, Analytical Profiles of Drug Substances, Volume 17, Academic Press 1988, pages 155-184

(28) Xian-Rui Liang et al, J. Chem. Eng. Data 2010, 55, 2340-2342

(29) Declaration of Carol Belanski dated 1 June 2012, filed by the appellant opponent with its statement of grounds of appeal

(33) DrugBank entry for sulfadiazine

(34) DrugBank entry for sulfamethizole

(35) DrugBank entry for sulfamethoxazole

(36) Experimental report filed by the appellant patentee with its statement of grounds of appeal

(39) WO 2008/136791

(40) J. Vercruysse and R.S. Rew (Ed.), Macrocyclic lactones in antiparasitic therapy, preface and chapter 1.1 "Ivermectin, Abamectin and Eprinomectin", 2002, CABI Publishing

(41) Summary of product characteristics of EPRINEX, revised in October 2010

(42) Declaration of Willy Blakely dated 19 October 2012, filed by the appellant patentee with letter dated 22 October 2012

(43) Declaration of Manish Umrethia dated 19 October 2012, filed by the appellant patentee with letter dated 22 October 2012

IV. The patent had been opposed on the grounds of Articles 100(c), 100(b) and 100(a) EPC, for lack of inventive step.

In the appealed decision, the opposition division concluded that the patent as granted (main request) fulfilled the requirements of Articles 123(2) and 83 EPC. However, it was considered to lack inventive step starting from document (2) as the closest prior art because the distinguishing feature in claim 1, "at least 30% (v/v) of ethanol", was regarded as being arbitrary. The subject-matter of auxiliary request 1

filed during oral proceedings was nevertheless found to meet the requirements of the EPC, and, in particular, to involve an inventive step by virtue of the restriction of the active ingredients to an avermectin and clorsulon.

V. With its statement of grounds of appeal, the appellant patentee filed auxiliary requests 1 to 4.

VI. With its reply to the appellant opponent's appeal, the appellant patentee filed auxiliary requests 5 to 9 .

VII. Claims 1 of auxiliary requests 1 to 9 contain the following amendments:

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request (patent as granted) in the selection of **clorsulon** as the anthelmintic sulphonamide.

Claim 1 of **auxiliary requests 2 to 4**, wherein auxiliary request 4 is identical to the auxiliary request held allowable by the opposition division, corresponds to claim 1 of auxiliary request 1 with the further limitation that the anthelmintic agent derived from *Streptomyces avermitilis* is an **avermectin.**

Claim 1 of **auxiliary requests 5 and 6** differs from claim 1 of auxiliary requests 2 to 4 in that the composition is presented as a **pour-on formulation.**

Claim 1 of **auxiliary requests 7 and 8** differs from claim 1 of auxiliary requests 5 and 6 in the limitation of the avermectin to **ivermectin.**

Claim 1 of **auxiliary request 9** differs from claim 1 of auxiliary requests 7 and 8 in the specification of the

content of ivermectin and clorsulon in the formulation as being **0.5% w/v and 5.0% w/v** respectively.

VIII. In a communication dated 9 March 2017, sent as annex to the summons to oral proceedings, the board *inter alia* noted that the admission of documents and auxiliary requests might have to be discussed during oral proceedings but that account had to be taken of the fact that all of the contested documents and requests had been filed either with the statements of grounds of appeal or in response thereto. Moreover, attention was drawn to the fact that none of the requests on file appeared to be entitled to the priority date of 21 January 2005, thus making document (20) prior art under Article 54(2) EPC. In addition, the board noted that, starting from document (2) as the closest prior art and taking into consideration the experimental evidence on file, the claimed formulation seemed to lack inventive step in view of documents (15) to (17), (20) and (27), an objection that would apply to all requests on file. Finally, the board indicated that claim 1 of auxiliary request 9 added subject-matter.

IX. With letter dated 23 March 2017, the appellant patentee announced that it would not attend the scheduled oral proceedings and requested that the proceedings take place in its absence.

X. By communication dated 13 July 2017, the board cancelled the oral proceedings appointed for 8 September 2017.

XI. The appellant opponent's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

Auxiliary requests 1, 2 and 5 to 9, filed for the first time in the appeal proceedings, should not be admitted because they are not clearly allowable and could have been filed in the opposition proceedings.

In addition, the documents filed by the appellant opponent with its statement of grounds of appeal should be admitted into the proceedings because they address points raised in the contested decision. In particular, documents (27) to (29) rebut the opinion of the opposition division that the selection of the ethanol content in claim 1 of the request allowed by the division (present auxiliary request 4) was purposive.

Concerning the issue of priority, the appellant opponent submitted that, although the specific embodiment at page 2, lines 28-32, of the priority document disclosed a formulation comprising 30% ethanol, this feature was not equivalent to the "at least 30% ethanol" feature present in claim 1 of all requests on file. Furthermore, the 30% ethanol feature in the priority application was only disclosed in the context of one particular formulation which contained specified amounts of certain other components. Accordingly, none of the requests on file was entitled to priority and document (20) was relevant prior art for the purpose of assessing inventive step.

As regards the assessment of inventive step, the appellant opponent concurred with the opposition division that document (2) represented the closest state of the art because it dealt with the problem of providing veterinary topical formulations that contained both a lipophilic and a hydrophilic anthelmintic in a single formulation. In this context, particular attention was drawn to the formulations of

examples 4 and 5, which contained the combination of avermectin or ivermectin with clorsulon. Alternatively, documents (3) and (14) were also proposed as starting points.

The formulation of claim 1 of all requests differed from the closest prior art as regards the carrier, which comprised at least 30% of ethanol together with isopropanol quantity sufficient to 100%.

In its analysis of the effect brought about by this difference, the appellant opponent submitted that the appellant patentee had claimed that this difference resulted in the dissolving of the active compounds, an essential requirement for the actives to be administered transdermally. However, the choice of at least 30% of ethanol was in fact arbitrary, as proven by the experimental evidence presented in document (29), which showed that the combination of 10% w/v clorsulon and 1.0% w/v ivermectin was completely dissolved at room temperature in pure isopropanol and in ethanol/isopropanol mixtures containing less than 30% (v/v) ethanol. In this context, the appellant opponent questioned the reliability of the experimental results presented by the appellant patentee in documents (36), (42) and (43). Documents (36) and (42) showed that clorsulon/ivermectin combinations comparable to those of document (29) were soluble in ethanol/isopropanol mixtures containing at least 30% ethanol but not in mixtures containing less than 30% ethanol, while document (43) reproduced the appellant opponent's tests from document (29) with results that corroborated the purposiveness of the at least 30% of ethanol feature. The reasons given by the appellant opponent for contesting the results of documents (36), (42) and (43) were: i) that said results were contrary

to what a skilled person would have expected knowing that ivermectin was soluble in isopropanol (see document (16)) and that clorsulon was soluble in methanol and ethanol (see document (15)); ii) that it was not credible that the actives could not be solubilised in 20% v/v ethanol and isopropanol to 100% after 24h at room temperature but that a relatively small increase in ethanol to 30% provided complete dissolution almost immediately; and iii) that the documents contained ambiguities and lacked essential information about how the tests had been carried out, e.g. the time point at which solubilities were measured, the use of heating or the experimental design of the tests.

In view of the lack of effect provided by the distinguishing feature, the appellant opponent formulated the problem to be solved as the provision of an **alternative** topical formulation that was capable of incorporating both a lipophilic (ivermectin) and a hydrophilic (clorsulon) drug in a single formulation. Then, it concluded that the solution proposed was obvious because the use of ethanol as solvent for anthelmintics was already known from documents (20), (9), (10), (12), (15) and (17) and, in particular, because document (20) taught that ethanol/isopropanol mixtures were suitable for use in pour-on formulations containing ivermectin in combination with parasiticidal agents of a different solubility profile.

XII. The appellant patentee's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

With respect to the issue of priority, the appellant patentee submitted that the subject-matter of claim 1

of the main request was implicitly disclosed at page 2, lines 20-26 and lines 28-32, of the priority application and that the skilled person would have derived it unambiguously from the priority application as a whole.

On the issue of inventive step, the appellant patentee argued that the subject-matter of the main request differed from document (2) not only in that the carrier comprised at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100% but also in that document (2) did not disclose a topical formulation comprising the anthelmintic agents cited in claim 1 of the patent because the compositions in examples 4 and 5 of document (2) were not intended for topical administration. They were rather variations of the formulation of example 1, which was a self-emulsifying microemulsion for injection. Hence, although document (2) stated at page 3, line 25 that the compositions could be easily adapted to be suitable for *inter alia* topical administration, this was not disclosed for the particular combination of ivermectin and clorsulon in the examples 4 and 5.

With regard to the effect provided by the feature "at least 30% (v/v) of ethanol", the appellant patentee referred to the transdermal anthelmintic effect shown in the examples of the patent and to the experimental evidence summarised in documents (36), (42) and (43) which, contrary to the results provided by the appellant opponent in document (29), showed the need for at least 30% (v/v) ethanol to achieve solubilisation of the actives of the invention.

Based on these differences and effects, the appellant patentee defined the problem to be solved as the

provision of a **topical composition suitable for transdermal delivery** of an anthelmintic derived from *Streptomyces avermitilis* (e.g. ivermectin) and an anthemlmintic of the sulphonamide type (e.g. clorsulon) in a single formulation.

In this context, the appellant patentee submitted that document (2) motivated the skilled person to prepare an oil-based composition which, through the presence of medium chain mono- and di-glycerides, would form a microemulsion upon dilution with water (see document (2): page 3, lines 21-22; page 4, lines 7-9; and claim 1). Hence, replacing the oily carriers of document (2) by the alcoholic mixture of the invention would not be an obvious solution to the problem posed, even if documents (20), (9), (10), (12) and (17) disclosed alcohol carriers. Firstly, because the cited documents contained drug combinations different from those of claim 1 and, secondly, because in order to find a carrier suitable for the transdermal delivery of two actives, several considerations were needed, e.g. solubility and stability of the actives, compatibility of the carrier with the animal or human to which it is to be administered, or the ability of the carrier system to facilitate effective transdermal delivery. In addition, with the exception of document (20), none of documents (9), (10), (12) and (17) mentioned isopropanol and ethanol in combination, let alone at the ratios required by claim 1. In this respect, particular attention was drawn to the fact that the combination partner of ivermectin in formulation 1 of document (20) was closantel, a compound with a chemical structure and a molecular weight considerably different to those of clorsulon. So, even if clorsulon and closantel had been formulated in an identical carrier system, the skilled person would not have expected them

to exhibit the same efficacy of penetration through skin upon topical application.

For the same reasons, the auxiliary requests should be regarded as inventive.

XIII. The appellant patentee requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims as granted (main request), or alternatively, on the basis of one of auxiliary requests 1 to 3, filed with the statement of the grounds of appeal dated 6 June 2012, or further alternatively, that the appellant opponent's appeal be dismissed, or further alternatively, that the decision under appeal be set aside and the patent be maintained on the basis of one of auxiliary requests 5 to 9, filed with the letter dated 22 October 2012. The appellant patentee further requested that the documents filed by the appellant opponent with its statement of the grounds of appeal not be admitted into the proceedings.

The appellant opponent requested that the decision under appeal be set aside and the patent be revoked in its entirety. It further requested that auxiliary requests 1, 2 and 5 to 9 as well as documents (33) to (36) and (39) to (43) not be admitted.

Reasons for the Decision

1. The appeals are admissible.

2. Announcement of non-appearance at oral proceedings

After having received a negative preliminary opinion from the board, the appellant patentee announced that

it would not attend oral proceedings and requested that the proceedings take place in its absence.

According to established case law, if oral proceedings are appointed as a result of a party's request for such proceedings on an auxiliary basis, and if that party subsequently states that it will not be represented at the oral proceedings, such a statement should normally be treated as equivalent to a withdrawal of the request for oral proceedings (see T 3/90, headnote).

Contrary to the case underlying the decision T 3/90, the appellant patentee's request for oral proceedings in the present appeal was unconditional (see statement of grounds of appeal, point 2.8). This difference, however, does not matter because the essence of T 3/90 is that there is no point in holding oral proceedings if a party aware of the board's negative opinion informs the board that it will not attend oral proceedings and will not present additional arguments – such a party has no legitimate interest in pursuing its request for oral proceedings. This view is in line with the decisions T 663/10 (see reasons, point 1.3) and T 910/02 (see reasons, point 6), which establish that, if a party informs the board that it does not intend to attend oral proceedings, the board is not obliged to hold oral proceedings in its absence. Rather, under these circumstances and irrespective of whether or not the party explicitly maintains its request for oral proceedings, it is at the board's discretion to decide whether the scheduled oral proceedings are to be maintained or to be cancelled, since it cannot be the purpose of Article 116 EPC that a party can oblige a board to hold oral proceedings in its absence.

The board therefore concludes that, taking into consideration the submissions of the parties in the written proceedings, the board's preliminary opinion of 9 March 2017 and the appellant patentee's letter of 23 March 2017, it is in a position to take a final decision without holding oral proceedings (Articles 113(1) and 116(1) EPC and Article 12(3) RPBA).

3. *Added subject-matter, clarity and sufficiency of disclosure*

In the written proceedings, the parties have discussed the compliance of the requests on file with Articles 83, 84 and 123(2) EPC. As the main request and the auxiliary requests 1 to 8 fail for other reasons (see points 6 to 8 below), the board does not need to decide on these issues. Regarding auxiliary request 9, see point 9 below.

4. *Admission of documents filed during the appeal proceedings*

Each of the parties has requested that the documents filed by the other party in the appeal proceedings not be admitted into the proceedings, yet neither party has substantiated its request.

Under the present circumstances, the board has decided to admit documents (27) to (29), (36), (42) and (43) into the proceedings (Article 12(4) RPBA), taking into consideration that they were filed with the statements of grounds of appeal or in response thereto and that they essentially reinforce the respective arguments of the parties in relation to the arbitrariness or purposiveness of the feature "at least 30% of ethanol",

which was a crucial aspect in the discussion of inventive step in the decision under appeal.

A decision on the admission of other documents is not necessary for the present decision. In particular, consideration of documents (33) to (35) and (39) to (41) is not needed because they were filed by the appellant patentee to counter arguments that do not require discussion in the present decision. Thus, documents (33) to (35) were intended to contest the opponent's inventive step argument that the solubility of sulphonamide anthelmintics would vary widely (see appellant patentee's statement of grounds of appeal, points 3.50 and 3.53); documents (39) and (40) were filed to address the objection of lack of clarity raised by the appellant opponent with regard to the term "an avermectin" in claim 1 of auxiliary request 4 (see appellant patentee's reply to the statement of grounds of appeal, points 4.12 and 4.13); and document (41) was submitted in response to an objection of lack of sufficiency of disclosure (see appellant patentee's statement of grounds of appeal, points 7.5).

5. *Priority and document (20)*

According to the appellant patentee, the feature "at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100%" was implicitly disclosed in the priority application at page 2, lines 20-26 and lines 28-32. The board, however, notes that the passage at page 2, lines 20-26, merely mentions that a useful carrier comprises alcoholic solvents and that the passage at page 2, lines 28-32, discloses a specific embodiment comprising *inter alia* 30% (v/v) ethanol and isopropanol to 100% (v/v). Consequently, the passages cited by the appellant patentee do not provide a basis

for ethanol concentrations greater than 30% (v/v), the latter constituting an intermediate generalisation which was not unambiguously disclosed in the priority application.

Following on from the above, none of the requests on file is entitled to the priority date of 21 January 2005 (Article 87(1) EPC), with the effect that document (20) belongs to the prior art under Article 54(2) EPC and can be used for the purpose of assessing inventive step.

6. Inventive step (main request)

The parties and the opposition division concurred that document (2) constitutes the closest prior art. The board accepts this view.

Document (2) relates to the preparation of veterinary compositions which incorporate a hydrophilic and a lipophilic active compound into a single formulation by the use of medium chain mono- and di-glycerides (see abstract; page 2, lines 20-21 and lines 29-33). In preferred embodiments, the hydrophilic active may be clorsulon (page 3, lines 8-9), the lipophilic active may be an avermectin (page 3, lines 6-7) and the composition may be adapted for topical administration (see page 3, lines 25-26). In addition, examples 4 and 5 disclose formulations comprising a combination of avermectin or ivermectin with clorsulon as active ingredient.

The parties and the opposition division considered that the formulation of claim 1 differs from those of document (2) in that the carrier comprises at least 30% (v/v) of ethanol together with isopropanol quantity

sufficient to 100%. In addition, the appellant patentee noted that, even though document (2) mentions that the compositions can be easily adapted to be suitable for topical administration, the formulations of examples 4 and 5 (i.e. those disclosing the combination of active compounds of claim 1) are not specifically disclosed for this use. The board accepts this additional difference and agrees with the appellant patentee's view that, on the basis of the mentioned differences, the problem to be solved may be formulated as the provision of a **topical composition suitable for transdermal delivery** of an anthelmintic derived from *Streptomyces avermitilis* (e.g. ivermectin) and an anthelmintic of the sulphonamide type (e.g. clorsulon) in a single formulation.

The board is convinced that this problem is solved by the formulation proposed in claim 1, which is characterised by having a carrier that contains at least 30% (v/v) of ethanol and isopropanol in quantity sufficient to 100%, because it is common general knowledge that **ethanol and isopropanol are customary carriers in anthelmintic pour-on formulations** (see e.g. document (16), item 2; document (17), page 3, lines 13-15; and document (20), page 7, lines 1-3 and formulations 1-3), that **ivermectin is soluble in both alcohols at transdermal therapeutic concentrations** (see document (27), page 166, table V; and document (16), items 1 and 2), and that **clorsulon is readily soluble in ethanol or methanol** (see document (15), page 3, paragraph 1). Accordingly, the combination of ivermectin and clorsulon is expected to dissolve in ethanol, isopropanol and mixtures thereof at transdermal therapeutic concentrations, and the resulting solution is expected to exhibit anthelmintic

effect by pour-on administration, thereby solving the problem posed.

For the same reason, however, it was obvious to the skilled person that any combination of ethanol and isopropanol was a carrier suitable for the transdermal delivery of an anthelmintic composition comprising ivermectin and clorsulon. In other words, the skilled person confronted with the problem posed would, starting from document (2) and in the light of the teaching of documents (15) to (17), (20) and (27), arrive at the formulation of claim 1 without the exercise of an inventive step (Article 56 EPC).

The appellant patentee argued that the selection of a carrier having at least 30% (v/v) of ethanol together with isopropanol to 100% was purposive and that this feature was essential to solve the problem posed, as evidenced by the experimental data provided in documents (36), (42) and (43) and in the patent. In particular, documents (36), (42) and (43) showed that a minimum ethanol concentration of 30% (v/v) was necessary to achieve dissolution of ivermectin and clorsulon at therapeutic doses, and the results of the studies presented in the patent showed a broad anthelmintic efficacy of the claimed formulation as a result of its effective transdermal delivery.

These arguments, however, have not convinced the board, which concurs with the opposition division and the appellant opponent that the feature "at least 30% (v/v) of ethanol together with isopropanol to 100%" is arbitrary for the following reasons:

(a) Regarding the argument on solubility, the tests filed by the appellant opponent with document (29)

prove that the combination of clorsulon and ivermectin at concentrations typical for these actives in pour-on formulations, namely 10% (w/v) clorsulon and 1% (w/v) ivermectin, was completely dissolved at room temperature in both pure isopropanol and ethanol/isopropanol mixtures containing less than 30% (v/v) ethanol. These tests are, in the board's judgment, more reliable than those showing the opposite effect in documents (36), (42) and (43) because the latter documents fail to specify essential details of the experimental procedure that cannot be ruled out as accounting for the discrepancy between their findings and the findings of document (29). Such missing details are, for instance, the time point at which solubilities were measured, the use of heating, and the experimental design. Accordingly, it has not been proven that the selection of at least 30% (v/v) of ethanol in the carrier of claim 1 results in a higher solubilisation of the active compounds.

(b) As for the argument of transdermal delivery by pour-on application, the board notes that the carrier of the composition tested in the patent (see paragraph [0015]) contains not only 30% of ethanol and isopropanol to 100% (both alcohols being known as carriers in pour-on formulations) but also 20% Crodamol Cap and 10% PEG200, which are additives that enhance solubility and efficacy of pour-on compositions (see e.g. document (14): page 7, lines 3-5 and examples 3, 6 and 8; and document (20): page 6, lines 25-27; page 8, lines 5-10; and page 8, lines 28-30). In consequence, the broad transdermal anthelmintic effect shown in the patent cannot be ascribed to the specific ratio ethanol/

isopropanol in the carrier and does not prove that the selection of a carrier containing at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100% provides an advantageous effect over carriers comprising other ethanol/isopropanol ratios.

As a result, the board concludes that the feature "at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100%" in claim 1 is arbitrary and does not contribute to inventive step.

7. *Admission of auxiliary requests 1, 2 and 5 to 9*

The appellant opponent requested that auxiliary requests 1, 2 and 5 to 9 not be admitted into the proceedings because they were not clearly allowable and could have been filed in the opposition proceedings.

Auxiliary requests 1, 2 and 5 to 9 were filed by the appellant patentee with its statement of grounds of appeal or in its response to the appellant opponent's statement of grounds of appeal and they represent, in the board's view, a reasonable reaction to the decision of the opposition division. Therefore, they have been admitted into the appeal proceedings (Article 12(4) RPBA).

8. *Inventive step (auxiliary requests 1 to 8)*

The assessment of inventive step of the main request was based on a pour-on anthelmintic formulation comprising the active ingredients ivermectin and clorsulon (see point 6). As such a formulation represents the subject-matter of claim 1 of any of auxiliary requests 1 to 8, the conclusion reached with

regard to inventive step for the main request applies *mutatis mutandis* to auxiliary requests 1 to 8.

9. *Added subject-matter (auxiliary request 9)*

The applicant cited claims 1, 4, 5, 6 and 10, and the passage on page 4, lines 8 to 11 as the basis in the application as filed for claim 1 of auxiliary request 9.

Claims 1, 4, 5, 6 and 10 depict a topical anhelmintic composition comprising ivermectin and clorsulon, wherein the carrier comprises at least 30% (v/v) of ethanol together with isopropanol quantity sufficient to 100%. The only passage cited by the appellant patentee which mentions a pour-on product formulation comprising 0.5% w/v ivermectin and 5.0% w/v clorsulon is page 4, lines 8 to 11, which refers to the specific formulation tested in the application examples. As said formulation appears to be the one disclosed on page 3, lines 17-24, which has a precise composition containing exact amounts of ethanol, isopropanol and other formulation ingredients, the formulation defined in claim 1 of auxiliary request 9 represents an unallowable generalisation thereof and adds subject-matter, contrary to Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated