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**Datasheet for the decision
of 14 May 2012**

Case Number: T 1324/09 - 3.3.02
Application Number: 01308417.3
Publication Number: 1197215
IPC: A61K 31/7048, A61K 9/10
Language of the proceedings: EN

Title of invention:
Anthelmintic compositions

Patentee:
Wyeth LLC

Opponent:
VIRBAC S.A.

Headword:
Anthelmintic compositions/WYETH LLC

Relevant legal provisions:
EPC Art. 56, 84

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request - clarity (no): composition of "MTM" and "MTC"
not known"
"Auxiliary request I - inventive step (no): obvious
combination"

Decisions cited:
T 0472/88, T 0420/00

Catchword:
-



Case Number: T 1324/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 14 May 2012

Appellant:
(Opponent)

VIRBAC S.A.
1 ere Avenue, 2065M LID
F-06516 Carros (FR)

Representative:

Bernstein, Claire Jacqueline
Cabinet ORES
36 Rue de St Pétersbourg
F-75008 Paris Cedex (FR)

Respondent:
(Patent Proprietor)

Wyeth LLC
Five Giralda Farms
Madison, NJ 07940 (US)

Representative:

Mannion, Sally
Avidity IP
Merlin House
Falconry Court
Baker's Lane
Epping
Essex CM16 5DQ (GB)

Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
23 April 2009 concerning maintenance of
European patent No. 1197215 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

- I. European patent No. 1 197 215 based on application No. 01 308 417.3 was granted on the basis of 11 claims.
- II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.
- III. The documents cited during the opposition and appeal proceedings included the following:
- (1) EP-A-0 329 460
 - (2) WO 98/06407
 - (3) EP-A-0-717 993
 - (9) GB-A-2 252 730
 - (10) Dictionnaire des Médicaments Vétérinaires et des Produits de Santé Animale, E. Meissonnier et al., Editions du Point Vétérinaire, 1997, pages 458-461
- IV. The appeal lies from an interlocutory decision of the opposition division, pronounced on 17 March 2009 and posted on 23 April 2009, finding that auxiliary request I met the requirements of the EPC.
- V. In said decision the opposition division decided that the claimed invention was sufficiently disclosed, as the selection of the various ingredients and their combination with further excipients for obtaining a suitable final product was within the common expertise of the skilled person. The routine experiments he might have to carry out in order to arrive at the final product did not constitute an undue burden. Regarding

the main request, the opposition division came to the conclusion that the subject-matter of claims 1 and 2 lacked novelty over document (3).

The subject-matter of auxiliary request I was novel, as neither document (2) nor document (3) disclosed compositions in which praziquantel was present in suspended form. Regarding inventive step, the opposition division defined document (9), which in example 5 disclosed a formulation comprising praziquantel and moxidectin, as the closest prior art. Starting from this prior art, it was not obvious to stabilise this composition with an antioxidant. In particular, the skilled person would not combine document (9) with document (1), which contained the teaching that adding antioxidants increased the shelf-life of S541 compounds, as the latter document was directed to single drug formulations. Even if he combined the teachings of these documents, he would end up with much lower antioxidant concentrations.

VI. The opponent (appellant) lodged an appeal against that decision.

VII. In the annex to the summons to oral proceedings pursuant to Article 15(1) RPBA, the board gave its preliminary opinion in connection with some of the points to be discussed at the oral proceedings, expressing the view that the subject-matter of the main request was novel over document (1) but appeared to lack inventive step over document (9), which was defined as the closest prior art, in combination with document (1).

VIII. With a letter filed on 13 April 2012, the respondent (patentee) submitted a new main request. The independent claims read as follows:

"1. An anthelmintic composition including moxidectin together with another anthelmintic compound, said anthelmintic compound being insoluble praziquantel, wherein the moxidectin is moxidectin in moxidectin technical material (MTM) or moxidectin technical concentrate (MTC), and the composition is stabilised by butylated hydroxytoluene (BHT) present in an amount of between 0.2% and 0.3% by weight of the total composition, the BHT being in addition to BHT present in the MTM or MTC.

3. A process of stabilising an anthelmintic composition including moxidectin together with another anthelmintic compound, said other anthelmintic compound being insoluble praziquantel, wherein the moxidectin is moxidectin in moxidectin technical material (MTM) or moxidectin technical concentrate (MTC), and the composition is stabilised by butylated hydroxytoluene (BHT) present in an amount of between 0.2% and 0.3% by weight of the total composition, the BHT being in addition to BHT present in the MTM or MTC.

5. A method of stabilising an anthelmintic composition including moxidectin and praziquantel, said praziquantel being in suspension, the method including the addition of between 0.2% and 0.3% of butylated hydroxytoluene (BHT) by weight of the total composition."

IX. Oral proceedings were held before the board on 14 May 2012. In the course of the oral proceedings, the

respondent filed auxiliary request I. The sole independent claim is identical to claim 5 of the main request.

X. The appellant's arguments can be summarised as follows:

Regarding the late submission of the experimental tests, reference was made to the statement of the grounds of appeal, in which the filing of these tests had been announced.

The composition of MTM and MTC was neither described in the contested patent nor part of the skilled person's general knowledge. As a consequence, there was lack of clarity.

Document (9), which constituted the closest prior art, disclosed suspensions comprising moxidectin, undissolved praxiquantel and a stabiliser. The selection of BHT as stabiliser was obvious in the light of document (1). The concentration range could not establish an inventive step either, because the skilled person would find the right concentration by routine experiments. The claimed concentration range was additionally rendered obvious by document (10), which disclosed compositions comprising among others moxidectin and 0.25% of BHT.

XI. The respondent's arguments can be summarised as follows:

The tests submitted by the appellant with letter dated 16 March 2012 were not admissible, as they had been filed too late for the respondent to be able to react adequately.

Regarding clarity in connection with claim 1 of the main request, it was argued that it was common practice to use technical concentrates. Even if the exact composition was unknown, the terms MTM and MTC were nevertheless clear, because what was important was the amount of BHT, which was clearly defined in the original application.

In connection with inventive step, document (9) was identified as the closest prior art, which was, however, not pertinent in view of the fact that it did not specifically relate to stability. Stabilisers were only mentioned in a laundry list of excipients. Its combination with document (1) did not lead to the invention according to claim 1 of auxiliary request I, as document (1) was completely silent about praxiquantel in suspended form and as BHT was used in much smaller amounts, which were perhaps sufficient for stabilising moxidectin alone but not for stabilising moxidectin plus praxiquantel.

XII. The appellant requested that the decision under appeal be set aside and that the European patent No. 1197215 be revoked.

The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 8 of the main request submitted on 13 April 2012 or, alternatively, claims 1 to 3 of the auxiliary request I submitted during oral proceedings of 14 May 2012.

Reasons for the Decision

1. The appeal is admissible.
2. Admission of the new requests
 - 2.1 Main request

The main request was submitted on 13 April 2012, i.e. one month before the oral proceedings before the board. In view of the fact that the amendments made were simple, straightforward and foreseeable and that the appellant did not raise any objections to its admission, the board admitted the main request into the proceedings (Article 13 RPBA).

- 2.2 Auxiliary request I

Auxiliary request I was filed at the oral proceedings before the board, i.e. at a very late stage of the appeal proceedings. However, in view of the fact that the amendments only concern the deletion of claims and that the only remaining independent claim was already present in the main request, the board admitted auxiliary request I into the proceedings (Article 13 RPBA).

3. Admission of the tests filed by the appellant with letter dated 16 March 2012

The appellant indicated in the statement of the grounds of appeal of 20 August 2009 that it intended to submit tests in connection with document (3), which show that the compositions disclosed therein comprise praziquantel

in suspended form. However, these tests were only filed with letter dated 16 March 2012, i.e. more than two and a half years later and less than two months before the oral proceedings before the board. As the appellant could not convincingly justify this long delay and as the respondent was deprived of the possibility to react adequately to this late submission, e.g. by running counter-experiments, the board decided not to admit these tests into the proceedings (Article 13 RPBA).

4. Main request - clarity

4.1 Moxidectin technical material (MTM) or moxidectin technical concentrate (MTC)

The composition according to claim 1 of the main request comprises moxidectin in the form of MTM or MTC. Neither of these terms is, however, defined in the patent in suit or known to the skilled person. It can be deduced from paragraph [0026] of the patent in suit that both MTM and MTC contain between 0.3 and 0.6% of butylated hydroxytoluene (BHT), but the further constituents thereof, if any, are not mentioned there. In the examples, an MTC comprising 0.49% BHT was used (see paragraph [0035] of the patent in suit). The above-mentioned paragraph [0026] also reveals that the commercially available products Cydectin[®] and Vetdectin[®] are prepared by using MTM or MTC as starting material. This information does not, however, allow any conclusion to be drawn as to the exact composition of MTM or MTC either. As a consequence, the terms MTM and MTC lack clarity.

4.2 Competence of the board to examine the clarity of the terms MTM and MTC in claim 1 of the main request

Claim 1 of the present main request is in essence a combination of claims 1 to 3 as granted, which means that the terms objected to under Article 84 EPC were taken from a granted dependent claim. As to the board's competence to address clarity issues under these circumstances, reference is made to decisions T 472/88 of 10 October 1990 (see point 2 of the reasons) and T 420/00 of 21 January 2003 (see point 3.6.3 of the reasons), according to which an ambiguity which arises from an amendment and subject to an objection under Article 84 EPC, is to be dealt with by the board under the power of Article 101(3) EPC (Article 102(3) EPC 1973). In this context, the word "arise" includes situations in which the amendment clearly highlights an ambiguity that has existed all along such as, as in the present case, a clarity problem which was hidden in a dependent claim and highlighted by incorporating the features of that dependent claim into the independent claim. The board therefore is competent to address this clarity issue.

4.3 As a consequence, the subject-matter of claim 1 of the main request does not meet the requirements of Article 84 EPC.

5. Auxiliary request I - inventive step

5.1 The present invention concerns a method of stabilising a anthelmintic composition comprising moxidectin and praziquantel (see paragraph [0010] of the patent in suit).

Document (9), which constitutes the closest prior art, relates to oral drenches comprising insoluble praziquantel and moxidectin, which may be further stabilised by a stabiliser (see page 2, line 28 to page 3, line 31).

- 5.2 In the light of this prior art, the problem of the invention according to claim 1 of auxiliary request I can be defined as the provision of a specific method for stabilising compositions comprising insoluble praziquantel and moxidectin. The solution proposed by the subject-matter according to claim 1 of auxiliary request I concerns the selection of BHT as stabiliser in an amount between 0.2 and 0.3% by weight of the total composition.

The board is convinced that the above-mentioned problem was solved in the light of the examples figuring in the original application.

- 5.3 Regarding the question whether the selection of BHT as stabiliser involves an inventive step, reference is made to document (1), which teaches that 23[E]-methoxyimino Factor A, which is identical to moxidectin (see page 3, lines 43-46, in combination with page 2, lines 27-51), can be stabilised with an antioxidant, preferably with BHT (see page 2, lines 52-59). As a consequence, the selection of BHT as stabilising agent for moxidectin cannot establish an inventive step.

It therefore remains to be evaluated whether the concentration range for BHT can contribute to an inventive step. In document (1), BHT is added in amounts

ranging from 0.005 to 1% with respect to the antibiotic compounds. In claim 1 of auxiliary request I, the BHT concentration is defined as 0.2 to 0.3% by weight of the total composition. Although a direct comparison between the two concentration ranges is not possible because of the different references on which they are based, the examples of document (1) (see examples 2 to 6 in which 250 ppm (= 0.025% by weight) of BHT was added) show that the BHT concentrations are lower in document (1) than in the method according to claim 1 of auxiliary request I. However, the optimal concentration can usually be determined with routine experiments which do not require inventive skill. It is an obvious step for the skilled person to increase the concentration of BHT if he discovers that the amounts proposed by document (1) do not yield optimal stability. In the present case, it is additionally noted that there is no evidence in the contested patent that the claimed BHT concentration of between 0.2 and 0.3% by weight of the total composition does indeed result in a more stable product as compared to a BHT concentration outside the claimed range. The board would point out in this context that the comparative studies (see examples III to V and in particular paragraph [0044] of the patent in suit) are not helpful, as they are all based on MTC, whose exact composition is not known (see point 4.1 above). It cannot be excluded that MTC or MTM comprise compounds other than BHT which might positively or negatively influence the stability of the moxidectin. Therefore, these studies have to be disregarded.

- 5.4 As a consequence, the subject-matter of claim 1 of auxiliary request I does not involve an inventive step (Article 56 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:

N. Maslin

U. Oswald