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**Datasheet for the decision
of 1 April 2014**

Case Number: T 1958/10 - 3.3.07

Application Number: 03711962.5

Publication Number: 1490037

IPC: A61K9/26, A61K9/00

Language of the proceedings: EN

Title of invention:

TASTE MASKED VETERINARY SOLID COMPOSITIONS

Patent Proprietor:

Novartis AG
Novartis Pharma GmbH

Opponent:

VIRBAC

Headword:

Relevant legal provisions:

EPC Art. 56
RPBA Art. 13

Keyword:

Inventive step - improvement not credible
- main request and auxiliary request I
Late-filed auxiliary requests - admitted (no)

Decisions cited:



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 1958/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 1 April 2014

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 July 2010 concerning maintenance of the
European Patent No. 1490037 in amended form.

Composition of the Board:

Chairman: J. Riolo
Members: D. Semino
W. Ungler

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies against the decision of the opposition division announced at the oral proceedings on 9 June 2010 to maintain European Patent 1 490 037 as amended. The patent was granted with 19 claims, independent claim 1 reading as follows:

"1. A animal medicine consisting of a substrate in pellet or tablet form, which is attractive to livestock and domestic animals and which consists of dry feed for animals on a vegetable and/or animal basis, in which fine-grained particles of a neutral-tasting, physiologically compatible, solid carrier material are embedded, which is characterised in that said fine-grained particles of carrier material have an average diameter of 0.09 to 0.8 mm and are coated with benazepril, and said benazepril layer is encased with a protective layer of a physiologically compatible polymer matrix."

II. A notice of opposition was filed against the granted patent requesting revocation of the patent in its entirety on the grounds of insufficiency of disclosure, lack of novelty and lack of inventive step in accordance with Article 100(a) and (b) EPC.

III. During opposition proceedings the following documents were *inter alia* cited:

D1: WO-A-01/37808

D2: WO-A-01/35925

D3: US-A-4 708 867

IV. The decision was based on a set of claims filed with letter of 2 June 2009 as main request. Claim 1 of the

main request was identical to claim 1 as granted, while in claims 16 to 18 an error had been corrected ("benazeprol" had been replaced by "benazepril")

V. The decision of the opposition division can be summarised as follows:

- a) The replacement of "benazeprol" with "benazepril" in claims 16 to 18 was an allowable correction of an obvious error.
- b) With regard to the term "neutral-tasting" and to the final particle size of the coated particles, sufficient guidance was given in the patent and there was no counter-evidence on the side of the opponent which could support lack of sufficiency. The objection to the term "sugar" was a clarity objection which is not a ground of opposition. The requirement of sufficiency was therefore met.
- c) Novelty of the subject-matter of claim 1 over document D1 was acknowledged, as several selection should be made in that document to arrive at the desired combination of features and in view of the feature of dry feed for animals on a vegetable and/or animal basis, which was not disclosed therein.
- d) The subject-matter of claim 1 was inventive over D2 taken as the closest prior art. The distinguishing features were the presence of benazepril as an active ingredient and the presence of particles of a neutral-tasting solid carrier material coated with an active agent. No improvement in acceptance, palatability, stability or homogeneity was shown, but it was credible that

the two-layer coating caused, when bitten, a smaller release of active agent. The problem solved was therefore the provision of an improved taste masking animal medicine composition for cardiac and renal insufficiency. No hint was found in the prior art to solve the posed problem by means of the distinguishing features. A combination with D3, which disclosed a double coating on neutral core, would not be obvious, as it addressed a different problem, did not mention biting of the particles and was not directed to animal feed medicine compositions, but to formulations for children and elderly patients. On that basis, the presence of an inventive step was acknowledged.

- VI. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant submitted *inter alia* a test report D16' ("Essais de prise de compositions alimentaires additionnées de b naz pril par des chats").
- VII. With the reply to the statement of grounds the patent proprietors (respondents) submitted *inter alia* a test report D19 ("Pilot Palatability/Acceptability Trial Fortekor[®] Flavour for Dogs").
- VIII. With letter of 11 October 2012 the respondents further submitted *inter alia* a further piece of evidence D23 (Package insert "FORTEKOR Flavor Tabs" by Novartis) and an auxiliary request. Claim 1 of the auxiliary request was identical to claim 1 as granted.
- IX. In a communication sent in preparation of oral proceedings the Board reviewed the submissions of the parties and in particular with regard to inventive step

pointed out *inter alia* the necessity to "analyse whether the evidence on file makes it possible to acknowledge the presence of improvements and advantages with respect to the closest prior art" (paragraph 3.3) and the fact that there was "apparently no evidence on file which makes a comparison with the products of D2 possible" (paragraph 3.4).

- X. With letter of 28 February 2014 the respondents renamed the auxiliary request filed with letter of 11 October 2012 as auxiliary request I and submitted three further sets of claims as auxiliary requests II, III, and IV.

Claim 1 of auxiliary request II corresponded to granted claim 1 with the addition that "the substrate which is attractive to livestock and domestic animals is lysed yeast". Claim 1 of auxiliary request III contained in addition the specification of the animal medicine being "for dogs". Claim 1 of auxiliary request IV corresponded to claim 1 of auxiliary request III with the further specification that "the physiologically compatible polymer matrix is a butyl methacrylate-(2-dimethylaminoethyl)methacrylate-methylmethacrylate copolymer (1:2:1)".

- XI. Oral proceedings were held on 1 April 2014.
- XII. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Main request - inventive step

- a) The animal medicine of claim 1 differed from the one of document D2, which represented the closest prior art, in that the active ingredient was

benazepril and in that this ingredient was coated onto the particles of carrier material instead of being mixed with it. No effect of the distinguishing features could be acknowledged. Benazepril had been on the market since the '80s and the commercial product did not cause any acceptance problem as confirmed by the tests in D16', which related to the administration of a daily dose of benazepril mixed with animal food. Even the tests of the respondent in D19 confirmed that benazepril did not cause any special difficulties in acceptance. Moreover, the specific active ingredient was just taken as an example in the application on which the patent was based, which mentioned an enormous number of possible active ingredients in a list which extended over several pages. Neither the examples in the patent, which did not even make it clear which product was tested, nor any other evidence available on file showed any improvement in stability or homogeneity with respect to the product of D2. Indeed the fact that a commercial product had been developed could not replace the need of evidence of an improvement in stability. As far as homogeneity was concerned, no feature of the claim was related to the homogeneity of the particle size or of the coating. No evidence was available that a smaller release of active ingredient would take place by rupture, nor that there were therapeutic benefits related to the specific formulation. Document D23 did not add more, as it related to a marketed product, for which no detail of the formulation was available. The problem solved was therefore simply the provision of an alternative taste-masking formulation. The choice of benazepril as active ingredient was just an arbitrary selection

among many possible alternatives and D2 itself mentioned a large number of classes of medicaments. Alternative taste-masking particles to be used for very bitter active ingredients were available from document D3, which disclosed particles with a neutral core coated with the very bitter active ingredient, which was further coated with a taste-masking polymer. Even if D3 concerned human medicines, it addressed the same problem of taste-masking which was equally relevant for humans and for animals. Moreover, the same specialist was concerned with human and veterinary pharmacy. On that basis, the product of claim 1 was not inventive.

Auxiliary request I - inventive step

- b) Claim 1 of auxiliary request I was identical to claim 1 of the main request and was therefore not inventive for the same reasons.

Auxiliary requests II, III and IV - admissibility

- c) Auxiliary requests II, III and IV were filed at a very late stage of the proceedings, shortly before the oral proceedings before the Board took place. They were not caused by any new ground or new fact introduced by the appellant or the Board. Together with being objectionable on the basis of lack of clarity, lack of sufficiency and lack of a basis in the original application, they introduced additional features which either did not provide any further effect (auxiliary requests II and IV) or did not add any structural difference to the product (auxiliary request III), so that their addition could not solve the lack of inventiveness

of the previous requests. On that basis, they should not be admitted into the proceedings.

XIII. The arguments of the respondents, as far as relevant to the present decision, can be summarised as follows:

Main request - inventive step

- a) The product of document D2 could be considered as the closest prior art in the absence of any better document in the proceedings disclosing animal medicines comprising benazepril. The differences of the product of claim 1 with respect to the disclosure in D2 were the replacement of the active ingredient with benazepril, which did not appear in the long list of medicaments of D2, and the specific particle structure with the double coating. There were several advantages with respect to the product of D2. Firstly, the particles of D2 were not suitable for masking the taste of a bitter medicaments, such as benazepril, which had to be taken by animals daily and for a long time and therefore required a large degree of acceptance, as they were not unitary in form, did not have a regular coating and were used for a medicaments to be taken only once a month. Document D16' was not suitable to show that the bitterness of benazepril was not an issue, as the quantity of active ingredient used in the tests of D16' was minimal. D19 showed that the acceptance of the claimed product was extremely high being similar to the one of a placebo. A better comparison could not be provided, as a reproduction of the product of D2 which contained a different active ingredient was not reasonable. The stability of the claimed animal medicine was

confirmed by the fact that it was an approved commercial product as shown by D23. The problem solved was therefore the provision of a medicament which was taste-masking for benazepril, had high palatability for animals and a good stability. There was no hint in the prior art that the problem could be solved by means of the claimed product. Benazepril was not present in most of the cited documents and, where it was mentioned, as in D1, it was only as a member of a very long list. In this respect it was relevant that previous commercial products containing benazepril were not in the proceedings. Document D3 was also not suitable to lead to lack of inventive step. Firstly, it had a different scope, as it concerned human medicine, and it was evident that the problems related to acceptance of a human medicine were very different from those of an animal medicament. Secondly, it disclosed minipellets to be spread on food and not particles to be embedded in a substrate. Finally, even if the teaching of D2 and D3 were combined, a product according to claim 1 would not be obtained, as neither concerned benazepril. In this respect it was relevant that benazepril was particular problematic, as far as taste-masking was concerned, in view of its bitterness, the necessity of taking a daily dose to treat serious illnesses and the acceptance problem of the previous commercial product. While it was true that the application as filed disclosed a long list of active ingredients, it only exemplified benazepril and both the long list in the original application and the one in D2 were of speculative nature. On that basis the present of an inventive step had to be acknowledged.

Auxiliary request I - inventive step

- b) The same arguments as developed from claim 1 of the main request applied to claim 1 of auxiliary request I which was identical thereto.

Auxiliary requests II, III and IV - admissibility

- c) Auxiliary requests II, III and IV were filed in reaction to the communication of the Board in which the respondent became aware for the first time that the data available might not be regarded as sufficient evidence for the presence of advantages with respect to D2. The amendments were clear and with a clear basis and added further preferred features of the product, which were not present in D2 and for which the evidence available (D19 and D23 in particular) was even more relevant, so that they addressed the issue of inventive step. They had therefore to be admitted into the proceedings.

XIV. The appellant requested that the decision under appeal be set aside and the patent be revoked.

XV. The respondents requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of auxiliary request I filed with letter of 11 October 2012 and of auxiliary requests II, III, and IV filed with letter of 28 February 2014.

Reasons for the Decision

Documents filed in appeal

1. The only documents filed in appeal which have been used by the parties in the arguments relevant for the current decision are D16', D19 and D23.
 - 1.1 D16' and D19 are test reports filed by the appellant with the grounds of appeal and by the respondents with the reply thereto respectively. Both of them are meant to support the respective view regarding whether advantages can be acknowledged for the claimed product with respect to the product of D2. They have been cited by both parties in their submissions and their admissibility has not been disputed.
 - 1.2 Also document D23, which has been filed by the respondents with letter of 11 October 2012, has been cited by both parties in their submissions and its admissibility has not been disputed.
 - 1.3 Under such circumstances the Board sees not reason to put into question the admissibility of documents D16', D19 and D23, which are therefore admitted into the proceedings.

Main request - inventive step

2. *Closest prior art*
 - 2.1 Document D2 was considered as the closest prior art in the decision under appeal and has been used as such in the majority of the arguments of the parties. The Board sees no reason to choose a different starting point for the analysis of inventive step. There was agreement

between the parties in the analysis of the disclosure of D2 as closest prior art and in the identification of the differences between the animal medicine of claim 1 of the main request and the disclosure of D2.

- 2.2 Document D2 discloses a food product for the oral delivery of a pharmaceutical agent to a non-human animal comprising particles of said agent dispersed substantially uniformly within a palatable food matrix, wherein each of said particles is encapsulated within a substantially inert coating (claim 1 and page 3, lines 23 to 26). The product is designed so that the unpleasant taste of the pharmaceutical agent is disguised (page 1, lines 3 to 4).
- 2.3 Solid food products according to D2 may be in the form of tablets with a food matrix of vegetable or animal basis (claims 6 and 9; page 4, lines 16 to 18; page 4, line 21 to page 5, line 2). The particles have preferably a diameter between 150 and 500 μm (page 7, lines 4 to 7) and according to the method of generation may have a core containing the pharmaceutical agent in a carrier (e.g. sodium alginate) encapsulated by the inert coating (page 8, line 9 to page 9, line 2). The inert encapsulating material is typically a physiologically compatible polymer, such as ethylcellulose, gelatine and gum arabic (page 8, lines 3 to 5).
- 2.4 While in the examples anti-worming compounds, such as fenbendazole and praziquantel, are specifically used as pharmaceutical agents (page 6, lines 5 to 10; examples on pages 10 to 13), it is disclosed in D2 that a large range of pharmaceutical agents may be included in the food products, including diuretics and cardiovascular preparations (page 5, lines 18 to 30).

2.5 The product of claim 1 of the main request differs therefore from the product of D2 in that the pharmaceutical agent is specifically indicated to be benazepril and is present in the particles in an intermediate coating layer between an inner neutral-tasting, physiologically compatible, solid carrier material and the encapsulated protective layer.

3. *Problem solved*

3.1 The main point of dispute between the parties relates to the identification of the effects and advantages of the claimed product with respect to the known one in view of the acknowledged differences and the consequent formulation of the problem solved.

3.2 The patent indicates that the claimed product solves the technical problems of previously known feed pellets (paragraph [0015]), namely "acceptance problems in the case of unpleasant tasting or unpleasant smelling active ingredient" (paragraph [0011]) and "stability problems" related to possible decomposition of the active ingredient during production and/or storage (paragraphs [0012] to [0014]). Indeed the respondents supported the view that benazepril was particularly problematic, as far as taste-masking was concerned, and that improved acceptance, palatability, stability and homogeneity of the product should be acknowledged, while the presence of these effects was contested by the respondents.

3.3 The evidence available on file has therefore to be analysed in order to determine which effects and advantages have been credibly shown and which problem has effectively been solved.

- 3.4 In the application as filed from which the patent under dispute originates no particular relevance is given to the choice of benazepril as the active ingredient. It is said that it "has been selected as the model active ingredient" (page 5, first full paragraph, first line) and that it "only represents a preferred embodiment of the present invention and is only intended to illustrate the invention by way of an application example" (page 5, last two lines). Moreover, many other possible active ingredients which can be administered according to the application are listed (pages 6 to 14) and no particular difficulty related specifically to benazepril is mentioned, apart from the general need to mask its taste due to its bitterness (page 5, first full paragraph, second sentence), which is in principle common to all ingredients for which taste-masking is necessary.
- 3.5 In D16' it is shown that cats accepted cat food with or without benazepril under different forms in the same way (see section III, "Conclusions"). Independently from the quantity of benazepril used in these tests (which according to the respondents was very small), these tests surely cannot support the presence of particular problems related to the masking of benazepril.
- 3.6 Even the tests filed by the respondents with D19, which show that a tablet of Fortekor[®] Flavour (allegedly according to the invention) had the same acceptability as a placebo (see section 3, "Summary and Conclusion") are not suitable to show that any specific problem existed for benazepril if administered in any way different from the claimed one.

- 3.7 Therefore the evidence on file does not support the presence of particular difficulties related to the masking of benazepril (which on the contrary does not appear to give peculiar masking issues in D16' and D19), so that the allegations of the respondents in this respect cannot be accepted for the formulation of the problem solved.
- 3.8 Also as far as the difference in structure between the animal medicine of D2 and the one of claim 1 of the main request is concerned (the presence of the pharmaceutical agent in an intermediate coating layer between an inner neutral-tasting, solid carrier material and an encapsulated protective layer), there is no comparison available on file, which is able to show that this modification leads to proven advantages.
- 3.8.1 In particular, there is no feature in claim 1 of the main request which is related to the homogeneity of the particle size of the fine-grained particles or to the homogeneity of their coating, nor is any evidence present, that by accomplishing the proposed change in structure a more homogeneous particle size or a more homogeneous coating would be obtained.
- 3.8.2 In addition, the fact that a product allegedly according to the invention was commercialised (as shown by the package insert "FORTEKOR Flavor Tabs" in D23) does not bring any evidence related to the comparison of the structure of claim 1 with the one of D2, which could similarly be expected to be reasonably stable.
- 3.8.3 Similarly, there is no evidence on file that by selecting the particle structure required by claim 1 of the main request with respect to the one in the product of D2 an improvement in acceptance or palatability of

the tablet should take place. In this respect the argument of the respondents that a better comparison than the one with a placebo as in D19 could not be provided, as a reproduction of the product of D2 which contained a different active ingredient was not reasonable, cannot be accepted, as the choice of the active ingredient appears to be an arbitrary one (see paragraph 3.4, above), so that an advantage related to the different particle structure could be acknowledged only in the presence of a direct comparison between tablets containing particles with the structure in D2 and tablets containing particles as required by claim 1 of the main request.

3.9 In view of this, the problem solved by the animal medicine of claim 1 of the main request with respect to the one of D2 is that of providing a further taste-masking animal medicine. The fact that the claimed animal medicine remains taste-masking is indeed considered to be credible in view of the presence of the protective layer for the fine-grained particles in the product of claim 1 of the main request as is the case in the product of D2.

4. *Obviousness*

4.1 It remains to be determined whether the choice of benazepril as active ingredient and the provision of double coated particles is an obvious solution to the posed problem.

4.2 Document D2 itself discloses that a large range of pharmaceutical agents may be included in the food products disclosed therein and provides a long list of classes of medicaments, including diuretics and cardiovascular preparations (page 5, lines 18 to 30).

- 4.3 Under such circumstances the arbitrary choice of an active agent out of the many possible medicaments falling under the general list of D2 (benazepril is known to treat cardiac and renal insufficiency, see paragraph [0019] in the patent under dispute) cannot support the presence of an inventive step.
- 4.4 Document D3 discloses minipellets which are coated to mask the unpleasant taste of active ingredients (column 1, lines 0 to 12). In order to achieve that, nonpareil sugar seeds, preferably 30-60 mesh in size (250 to 595 μm) are coated with a suspension or solution of the active ingredient and then further coated with an organic solution of dimethylaminoethyl and methyl methacrylate (column 2, lines 1 to 11). The active ingredient is prednisone or prednisolone, having a very bitter taste, unpleasant to adults and particularly unpleasant to children (column 1, lines 9-10 and 19-21).
- 4.5 The skilled person, while looking for a further taste-masking animal medicines, starting from the one of D2 which includes fine-grained particles, would learn from D3 that alternative taste-masking fine-grained particles have the active ingredient in an intermediate coating layer between an inert core and the encapsulating polymer coating.
- 4.6 Moreover, the particles of D3 would be readily suitable to be used within the animal medicine of D2. Neither the fact that the particles of D3 are not embedded into a matrix, but are contained in a capsule and then spread onto food, nor the fact that the active ingredient of D3 is used to treat humans would dissuade the skilled person to use the particles of D3 in the

animal medicines of D2, as the particles developed in the two documents address the same issue (taste-masking, see points 2.2 and 4.4, above), they follow the same basic principle of taste-masking by means of an external physiologically compatible polymer coating layer and they even have the same preferred particle size.

4.7 The skilled person, therefore, starting from the animal medicines of D2 and looking for further taste-masking animal medicines, would alternatively use fine-grained particles with the active ingredient in an intermediate coating layer between the inert core and the encapsulating polymer coating following the teaching of D3 and apply the resulting structure to an arbitrarily selected active ingredient without exercising any inventive activity.

4.8 It follows that the animal medicine of claim 1 of the main request does not involve an inventive step.

Auxiliary request I - inventive step

5. Claim 1 of auxiliary request I is identical to claim 1 of the main request. The product of claim 1 of auxiliary request I therefore does not involve an inventive step for the same reasons as outlined for the product of claim 1 of the main request (points 2 to 4, above).

Auxiliary requests II, III and IV - admissibility

6. Auxiliary requests II, III, and IV were submitted by the respondents with letter of 28 February 2014, shortly before the oral proceedings before the Board

and well after these oral proceedings had been convened.

6.1 These requests cannot be considered as a reaction to any new situations having arisen at a late stage of the proceedings. In particular they cannot be seen as a reaction to the communication of the Board in which the submissions of the parties were reviewed, consideration on inventive step were made which form part of the common application of the problem-solution approach (e.g. the need to analyse the evidence on file to investigate the presence of improvements or advantages with respect to the closest prior art) and a statement on such evidence was made ("There is apparently no evidence on file which makes a comparison with the products of D2 possible", see point IX, above) which corresponded to the position of the appellant in the statement of grounds. No other possible justification for the late filing has been provided by the respondents.

6.2 The added features (the specification that the substrate is lysed yeast, that the medicine is one for dogs and that the polymer matrix of the protective layer is a specific one) do not appear to give a possible contribution to the inventiveness of the claim, as, even if they possibly constitute further differences with respect to the product of D2, there is no effect related to their presence which has been supported with evidence (or even claimed to be present) by the respondents, nor any argument that they might constitute non-obvious alternatives.

6.3 As there is no justification for the late filing of the requests and it is not apparent how they could solve the crucial issue of lack of inventive step, the Board

on exercise of its discretion under Article 13(1) of the Rules of Procedure of the Boards of Appeal finds it appropriate not to admit auxiliary requests II, III and IV into the proceedings.

Conclusions

7. As all requests which are admitted into the appeal proceedings fail for lack of inventive step, there is no need for the Board to decide on any other issue and the patent is to be revoked.

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:



L. Fernández Gómez

J. Riolo

Decision electronically authenticated