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**Datasheet for the decision
of 26 April 2016**

Case Number: T 1901/12 - 3.3.09

Application Number: 04763629.5

Publication Number: 1675474

IPC: A23K1/18, A23K1/17, A23K1/00,
A23K1/16, A61K9/00

Language of the proceedings: EN

Title of invention:

PALATABLE DUCTILE CHEWABLE VETERINARY COMPOSITION

Patent Proprietor:

Novartis Tiergesundheit AG
Novartis Pharma GmbH

Opponent:

VIRBAC S.A.

Headword:

Relevant legal provisions:

EPC Art. 54(2), 54(3), 56, 83
RPBA Art. 13(3)

Keyword:

Admissibility of new main request - (yes)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1901/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 April 2016

Appellant: VIRBAC S.A.
(Opponent) 1 ere Avenue, 2065M LID
06516 Carros (FR)

Representative: Nony
11 rue Saint-Georges
75009 Paris (FR)

Respondent 1: Novartis Tiergesundheit AG
(Patent Proprietor 1) Werk Rosental
Schwarzwaldallee 215
WRO-1032
4058 Basel (CH)

Respondent 2: Novartis Pharma GmbH
(Patent Proprietor 2) Brunner Strasse 59
1230 Wien (AT)

Representative: Sexton, Jane Helen
J A Kemp
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
29 May 2012 maintaining European patent No.
1675474 in amended form.

Composition of the Board:

| | |
|-----------------|------------------|
| Chairman | W. Sieber |
| Members: | N. Perakis |
| | D. Prietzel-Funk |

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the opponent against the interlocutory decision of the opposition division to maintain European patent No. 1 675 474 in amended form.
- II. An opposition was filed under Article 100(a) EPC (lack of novelty and inventive step) and Article 100(b) EPC (insufficient disclosure). During the oral proceedings before the opposition division the opponent introduced a new ground under Article 100(a) EPC (method of treatment of an animal body by therapy), which was admitted into the proceedings by the opposition division.

The documents cited included the following:

- D1: EP 1 247 456 A2;
D3: US 6 500 463 B1;
D7: WO 02/00202 A1;
D8: US 2001/0036464 A1;
D14: Starch 1500[®] Partially pre-gelatinized Maize Starch, Colorcon, 1999;
D15: Certificate of Analysis of Starch 1500[®] Partially pre-gelatinized Maize Starch, Colorcon P.R.Inc, 2 July 2004; and
D19: WO 2004/016252 A1.

- III. The opposition division maintained the patent in amended form on the basis of claims 1 to 60 as granted and a reformulated claim 61 as filed during the oral proceedings. Claims 1, 30, 33 and 61 read as follows:

"1. A highly palatable ductile chewable veterinary composition comprising (A) an affective-amount of one

or more ingredients that are active against animal pests, pathogens or animal diseases; (B) meat flavoring; (C) partially gelatinized starch; (D) a softener; and (E) up to 9% water."

"30. Process for the production of a highly palatable ductile chewable veterinary composition of claim 1, comprising (i) feeding the hopper of an extruder with an effective amount of one or more ingredients that are active against animal pests, pathogens or animal diseases; meat flavoring; partially gelatinized starch; a softener; and up to 9% (w/w) of water; (ii) cooling constantly down the mixture of active ingredients and carriers so that the temperature of the extrudate that leaves the tip of the extruder does during the whole extrusion process at no time exceed 40°C, (iii) pressing the extrudate through a die that is decisive for the shape of the chewable product, and (iv) cutting the extrudate that leaves the extruder into equal pieces."

"33. Use of (A) an effective amount of one or more ingredients that are active against animal pests, pathogens or animal diseases; (B) meat flavoring; (C) partially gelatinized starch; (D) a softener; (E) up to 9% water; and an active ingredient suitable for combating animal pests, pathogens or animal diseases for the preparation of a highly palatable ductile chewable veterinary composition."

"61. A highly palatable ductile chewable veterinary composition of claim 1 for use in a process of controlling nonhuman animal pests or nonhuman pathogens or of curing or preventing nonhuman animals diseases."

IV. As regards sufficiency of disclosure, the opposition division considered that (i) the patent provided the skilled person with enough information to produce a palatable composition with a meat flavouring and a partially pre-gelatinized starch, and (ii) the choice of the active agent was based on standard veterinary procedures within the purview of the skilled person.

As regards novelty, the opposition division considered that none of D1, D7, D8 and D19 disclosed the composition of claim 1. D19, a document cited under Article 54(3) EPC, filed late and admitted into the proceedings as *prima facie* relevant, did not disclose that the starch was partially gelatinized. Moreover, according to the understanding of the skilled person the term "partially gelatinized" comprised one type of starch, a portion of which had been gelatinized, but did not refer to a mixture of a pre-gelatinized with a non pre-gelatinized starch as disclosed in D19.

As regards inventive step, the opposition division considered that none of the cited documents, namely D1 and D7, and none of the alleged combinations, namely D8 with D4 or D3 with D4, rendered the claimed subject-matter obvious to the skilled person.

Regarding the alleged unallowable method of treatment of an animal body by therapy in claim 61 as granted, the patent proprietors overcame this objection by reformulating the wording of this claim during the oral proceedings.

V. On 26 July 2012 the opponent (in the following the appellant) filed an appeal against the decision of the opposition division. In the statement setting out the grounds of appeal the appellant reiterated the

objections raised before the opposition division and additionally raised an objection of lack of clarity against claim 61 as upheld by the opposition division. The following additional documents were filed:

- D7a: US 2004/0043925 A1 (US family member of D7);
- D21: WO 92/15285 A1;
- D22: Sheskey *et al*, Dow product information, "Evaluation of Various Polymers As Dry Binders in the Preparation of an Immediate-Release Tablet Formulation by Roller Compaction", *Pharmaceutical Technology*, 1995, pp98-112;
- D23: EP 0 679 400 A1;
- D24: WO 96/02525 A1;
- D25: EP 0 747 050 A1;
- D26: WO 97/44022 A1;
- D27: WO 00/53149 A2;
- D28: WO 03/001901 A2;
- D29: EP 1 302 205 A1;
- D30: WO 03/032922 A2;
- D31: WO 03/066029 A2;
- D32: WO 03/066030 A2;
- D33: WO 03/053399 A2;
- D34: US 2011/0311483 A1;
- D35: The Merck Index, 14th edition, 2006, entry 7855, Propylene Glycol; and
- D36: US 3 849 582 A.

VI. In their response, the patent proprietors (in the following the respondents) requested that the appeal be dismissed or that the patent be maintained on the basis of auxiliary requests 1 to 7 filed with that letter. They also requested that late-filed documents D7a and D21 to D36 not be admitted into the proceedings.

VII. Subsequently the appellant raised an objection under Article 123(3) EPC against the subject-matter of claim 61 as upheld by the opposition division, reiterated the objections previously raised and filed observations on the auxiliary requests of the respondent. The appellant filed additional documents D37 and D38:

D37: Technical Bulletin, Starch 1500[®] Partially pre-gelatinized Maize Starch, Colorcon, 2012;

D38: Excipients, Starch 1500[®], Partially pre-gelatinized Maize Starch, Colorcon, 2014.

VIII. By letter of 11 March 2016, the respondents filed further submissions accompanied by new requests, namely a main request and auxiliary requests 1 to 7. The main request corresponded to the previous main request with the difference that claim 61 had been deleted. Only the main request is relevant for this decision.

IX. By letter of 21 March 2016, the appellant objected to the admissibility of the new requests filed by the respondents.

X. On 26 April 2016, oral proceedings were held before the board.

XI. The relevant arguments put forward by the appellant in its written submissions and at the oral proceedings may be summarised as follows:

- The new main request submitted with the letter dated 11 March 2016 should not be admitted into the proceedings in view of Article 13(3) RPBA. The appellant was not in a position to deal with the new request in the short time up to the date of the

scheduled oral proceedings and to determine whether the new request overcame the issues raised.

Furthermore, the submission of the new request was not justified, as the objections of the appellant had been known since the beginning of the appeal proceedings.

- The invention underlying the subject-matter of claim 1 of the main request was not sufficiently disclosed. The patent did not provide the skilled person with the necessary information enabling him to obtain a highly palatable, ductile and chewable veterinary composition, in particular the essential information according to the description regarding:
 - the degree of gelatinization of the partially gelatinized starch;
 - the amount of the meat flavouring and its fat content;
 - the nature of the softener; and
 - the proportion of meat flavouring and partially gelatinized starch.
- The subject-matter of claim 1 lacked novelty in view of D19, a prior-art document under Article 54(3) EPC, D1, D3, D7 and D8. When reading these documents the skilled person would be aware, on the basis of his common general knowledge illustrated by D21 to D34 and D36 and in view of the patent in suit, that the terms "partially gelatinized starch" and "pre-gelatinized starch" were interchangeable. Thus any reference in those

documents to "pre-gelatinized starch" clearly and unambiguously meant "partially gelatinized starch".

- On the one hand, the components of the claimed composition were disclosed in various parts of D19 and the skilled person would have directly and unambiguously combined them and would have obtained the palatable, ductile and chewable veterinary composition of claim 1. On the other hand, example 3 disclosed the claimed composition. The pre-gelatinized starch used in example 3 was obtained by the company Colorcon, which according to D37 and D38 was marketing only two starches at the priority date of the patent, which were disclosed to be partially gelatinized starches. Apart from that, the composition of example 3 included two kinds of starch, one pre-gelatinized and the other non gelatinized, the mixture of which implicitly provided a partially gelatinized starch.
- D1 disclosed the components of the claimed composition in various parts of the description, in particular a pre-gelatinized starch component. Thus the skilled person would have combined them and would have directly and unambiguously obtained the palatable, ductile and chewable veterinary composition of claim 1. Contrary to the assertions of the respondents, D1 disclosed that the composition was chewable.
- D3 disclosed a palatable, ductile veterinary composition, which fell within the definition of claim 1. In particular, it comprised a partially gelatinized starch (column 24, lines 10-34) and had a water content lower than 8% by weight (column 23, lines 41-42). Regarding the flavouring, it was

implicitly a meat flavouring since the composition was directed to carnivorous animals. Thus D3 disclosed all features of claim 1.

- D7 disclosed a palatable veterinary composition which comprised a pre-gelatinized starch (page 19, line 26: "vorbehandelten Stärke wie vorgekochte") and thus anticipated the composition of claim 1.
- D8 disclosed a veterinary composition comprising a pre-gelatinized starch (paragraph [0008]) and a water content as low as 5% (paragraph [0016]). Regarding the meat flavouring, it was disclosed in D8 since it described chicken fat and prime-steam lard (paragraph [0012]). Thus D8 disclosed the subject-matter of claim 1.
- Claim 1 did not involve an inventive step. Many documents could be considered as the closest prior art in view of the problem set out in the patent. Consequently, more than one line of argumentation was possible. The claimed subject-matter lacked an inventive step in view of the obvious combinations of D1 with D3, D3 with D1, D7 or D8, and D7 with D3. Furthermore, the claimed subject-matter lacked inventive step also because the claim did not contain the essential features for obtaining the alleged advantageous technical effects and thus the technical problem was not solved over the entire scope of the claimed subject-matter.

XII. The relevant arguments put forward by the respondents in their written submissions and at the oral proceedings may be summarised as follows:

- The main request filed with the letter of 11 March 2016 should be admitted into the proceedings. It consisted of claims 1 to 60, which were part of the interlocutory decision of the opposition division. The mere deletion of claim 61 from the claims upheld aimed at streamlining the procedure, and was a reaction to the appellant's lengthy submissions. The deletion of claim 61 did not give rise to new issues.

- Document 7a should not be admitted into the proceedings due to its late filing and its irrelevance. Documents D21-D36 should also not be admitted into the proceedings since they introduced confusion regarding the terms "pre-gelatinized starch" and "partially gelatinized starch", which were, in fact, different. The first provided a time-related definition of the starch, while the second defined the starch by its degree of gelatinization.

- The invention underlying the subject-matter of claim 1 fulfilled the requirements of sufficiency. The appellant, who had the burden of proof, had not provided any evidence to support the assertion that essential features were missing and that the skilled person based on the patent specification and using his common general knowledge was unable to carry out the invention across the entire scope of the claim.

- The subject-matter of claim 1 of the main request was novel over all cited documents. The objection of the appellant was essentially based on an incorrect understanding of the term "pre-gelatinized starch" used in the patent and the

prior art and the incorrect assumption that these terms were interchangeable. Whereas "partially gelatinized starch" described the degree of starch gelatinization, "pre-gelatinized starch" related, in the absence of any specific technical context, to the process of gelatinization in general without any specific degree of gelatinization and concerned starch which was either partially or completely gelatinized.

- Contrary to the assertions of the appellant, D19 did not clearly and unambiguously disclose the combination of the features of claim 1. In particular, example 3 did not disclose a partially gelatinized starch but a pre-gelatinized starch. Although the latter was obtained from the company Colorcon, it had not been shown that Colorcon was only marketing partially gelatinized starch at the priority date of the patent in suit. Moreover, in view of D37, the skilled person would not consider the mixture of a pre-gelatinized with a non-gelatinized starch as a partially gelatinized starch but as a co-processed excipient.
- D1, D7 and D8 only disclosed pre-gelatinized starches, which were not clearly and unambiguously partially gelatinized. Thus, on the basis of this difference alone, the subject-matter of claim 1 was novel over D1, D7 and D8.
- D3 disclosed the use of a partially gelatinized starch, but it did not disclose that the flavouring was a meat flavouring, that the composition was chewable or that the water content was up to 9%.

- Claim 1 involved an inventive step. The technical problem cited in the patent was to provide a composition acceptable to animals in terms of palatability, ductility and chewability, and which showed sufficient stability of the heat-sensitive active ingredient and flavouring since it allowed extrusion at temperatures not exceeding 40°C (paragraphs [0001], [0021], [0028] to [0030] and [0133]).

- Contrary to the assertions of the appellant, the problem was solved over the entire scope of claim 1. Although the examples showed the best mode to carry out the invention, the problem was also solved, albeit less effectively, over the whole claimed range. The appellant, who bore the burden of proof, had not provided any evidence that the problem (i) was not solved because of the lack of essential features or (ii) was not solved over the entire scope claimed.

- D1 was considered to represent the closest prior art. It concerned pharmaceutical palatable veterinary compositions for oral administration and comprised active ingredients and a meat flavouring.

- D3, D7 and D8 were more remote than D1 from the claimed subject-matter and the skilled person would not have considered them as appropriate closest prior-art documents. D3 concerned the encapsulation of sensitive components and did not deal with the chewability and palatability of veterinary compositions. D7 disclosed a process in which the extrusion was carried out at a temperature of 120°C, unacceptable for unstable active ingredients. Moreover, D7 did not disclose a

partially gelatinized starch. D8 did not use a partially gelatinized starch, disclosed a water content higher than 9%, which would lead to storage difficulties, and involved higher extrusion temperatures undesirable for sensitive components such as active ingredients and flavouring.

- The claimed composition differed from that of D1 in that it contained a partially gelatinized starch and that it was chewable and ductile.
- The technical problem in view of D1 was the provision of a chewable, ductile composition which was stable both during extrusion and storage.
- The solution was not suggested in the prior art. The skilled person would not consider D7 and D8 since they did not disclose a partially gelatinized starch but a pre-gelatinized starch, and since they involved higher extrusion temperatures, detrimental to the stability of the active ingredients and the meat flavouring. The skilled person would also not consider D3, despite the fact that it disclosed partially gelatinized starch among other kinds of starch, since it dealt with a different technical problem, namely improved encapsulation of the pharmaceutically active ingredient in order to provide stability during further processing. In fact, D3 did not concern the improvement of palatability, chewability and ductility of the composition. In conclusion, the skilled person would not combine D1 with any of D3, D7 and D8.

XIII. The appellant requested that the decision of the opposition division be set aside and that the patent be revoked.

XIV. The respondent requested that the patent be maintained on the basis of claims 1 to 60 of the main request filed with the letter dated 11 March 2016, including description pages 2 to 20 as filed during the oral proceedings.

Reasons for the Decision

1. Admission of the main request

The appellant requested that the new main request filed a month and a half before the oral proceedings not be admitted into the proceedings under Article 13(3) of Rules of Procedure of the Boards of Appeal.

However, the board notes that the new main request differs from the previous main request, i.e. the claims upheld by the opposition division (see above point IV), merely by the deletion of "the composition for use" claim (claim 61). The deletion of this claim did not have any impact on the scope of the appeal as regards the remaining claims, did not raise issues which the board and the appellant could not reasonably be expected to deal with without adjournment of the oral proceedings, and was carried out to streamline the procedure by avoiding a possibly lengthy discussion on the allowability of claim 61. In view of this, the board admitted the main request into the proceedings.

2. The late-filed documents D7a and D21-D36

Document D7a is a post-published, English patent family member of D7 (in German). It was only used by the appellant for ease of reference to the relevant

passages of D7. Since the appellant eventually relied on D7 itself, there was no need to decide on the admission of this document.

2.1 D21 to D34 and D36 were submitted as *prima facie* relevant as to the technical meaning of the term "pre-gelatinized starch", a key issue for novelty and inventive step. They were thus admitted into the proceedings.

2.2 D35 relates to the common general knowledge as regards the term "propylene glycol" and thus was also admitted into the proceedings.

3. Sufficiency

3.1 The appellant contested the sufficiency of disclosure on the ground that claim 1 did not contain all essential features necessary to reproduce the effects of the claimed invention, namely

- the degree of gelatinization of the partially gelatinized starch;
- the amount of the meat flavouring and its fat content;
- the nature of the softener; and
- the proportion of meat flavouring and partially gelatinized starch.

3.2 According to the appellant, paragraph [0129] of the patent specification disclosed that the degree of gelatinization of the partially gelatinized starch was

an essential feature and required a pre-gelatinized starch content of 10-20% w/w.

The paragraph in question reads as follows:

"The second important feature of the present invention is the use or (sic) partially gelatinized starch. This starch contains 10-20% (w/w), preferably about 13-17% (w/w), most preferably 13-17% (w/w) pre-gelatinized starch. This is important as non-gelatinized and completely pre-gelatinized starch do not result in the desired ductility of the final product."

The minimal requirement expressed by that wording is that the starch has to be partially gelatinized. This is exactly what claim 1 requires. Therefore, the board cannot accept the appellant's argument. If anything, there might be an inconsistency between the first and second phrase of this paragraph. However, this is rather an issue of clarity than of sufficiency.

3.3 As to the amount of the meat flavouring and its fat content the appellant referred to paragraph [0126] of the patent specification which states:

"It has surprisingly been recognized that the desired high palatability that is necessary for achieving reliable and well-reproducible results strictly depends on the amount of meat flavoring in the final composition. ... It further surprisingly turned out that the natural content of fat in said natural meat powder of 20-55% (w/w) is very important not only for achieving the desired high palatability and excellent taste for the animal but also for achieving the desired softness of the final chewable product. ... It has however be recognized that artificial meat flavorings

are only suitable for the present invention if they already contain 20-55% fat or if this amount of fat is added to the artificial flavoring".

This passage provides the skilled person with the required information relating to the fat content to be used with the meat flavouring. Furthermore, the skilled person on the basis of his common general knowledge is able to determine the amount of the meat flavouring necessary to provide the required palatability of a veterinary composition for a specific animal. In fact, it has not been disputed that various meat flavourings were already known in the art and were used to improve the palatability of animal food. The patent in suit makes explicit reference to commercially available meat flavourings (see page 15, line 51 to page 16, line 9). The fact that the amounts of the above constituents are absent from the claimed subject-matter does not mean that the skilled person does not find in the patent as a whole the necessary information.

3.4 According to the appellant, the type of softener is essential since it keeps the moisture within the composition and allows the final product to be stored for weeks and months without drying out (see paragraph [0131]). Nevertheless, suitable softeners are explicitly disclosed in paragraph [0139], the latter providing the skilled person with the necessary information regarding this component.

3.5 Also the proportion of the meat flavouring and the partially gelatinized starch was alleged to be essential in view of paragraph [0133] of the patent, which states:

"For the present invention not only the proportion of meat flavouring and partially pre-gelatinized starch is extremely important... ."

However, the patent contains examples which disclose this proportion. Furthermore, the skilled person is able on the basis of his common general knowledge to determine this proportion in different situations.

3.6 It appears that the appellant's objections with regard to the amount of the meat flavouring and its fat content, the nature of the softener, and the proportion of meat flavouring and partially gelatinized starch relate rather to Article 84 EPC (support by the description) than to sufficiency of disclosure. Such an objection under Article 84 EPC cannot be raised against claims 1 to 60 of the main request, because these are granted claims. Furthermore, no evidence whatsoever has been provided that the alleged deficiencies under Article 84 EPC amount to insufficiency.

3.7 Lastly, the appellant argued that not any combination of the five components of claim 1 would necessarily provide a highly palatable, ductile and chewable veterinary composition. This put an undue burden on the skilled person, who had to carry out a research programme in order to find out which combinations provided the effect sought.

However, in the board's view the skilled person is able on the basis of his common general knowledge to put the invention into practice following the instructions of the patent. Particular reference is made to the examples of the patent which reproduce the claimed invention successfully. Furthermore, as pointed out by the respondents, the appellant, who bears the burden of

proof, has not submitted any technical evidence to show that the invention was not reproducible or not reproducible over the whole range claimed.

3.8 In view of the above, the board concludes that the invention underlying claim 1 is disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. Novelty

4.1 Meaning of "partially gelatinized starch"

Claim 1 requires the use of partially gelatinized starch. The appellant asserted that the terms "partially gelatinized starch" and "pre-gelatinized starch" were interchangeable. This issue, which was contentious between the parties, needs to be addressed before assessing novelty of the claimed subject-matter.

4.1.1 It is common general knowledge that starch gelatinization is a process of breaking down the intermolecular bonds of starch molecules in the presence of water and heat, allowing the hydrogen bonding sites (the hydroxyl hydrogen and oxygen) to engage more water.

The term "partially gelatinized starch" describes, as indicated in paragraph [0129] of the patent (see above point 3.2), a starch having gelatinized and non-gelatinized starch. In particular, completely gelatinized or completely non-gelatinized starch is not encompassed by this term, as expressly stated in paragraph [0129]. In other words, this term defines the degree of gelatinization.

On the other hand, the term "pre-gelatinized starch" refers to starch which has undergone a process of gelatinization prior to being used. Pre-gelatinized starch, in the absence of any other context, does not indicate the degree of gelatinization. It may be completely or only partially gelatinized.

Thus, on the face of it, the terms are not interchangeable.

There was, however, agreement between the parties that the "partially gelatinized starch" to be used in the composition of claim 1 is necessarily pre-gelatinized. In other words, a "partially gelatinized starch" is not different from a "partially pre-gelatinized starch".

4.1.2 In support of its assertion that the terms "partially gelatinized starch" and "pre-gelatinized starch" were interchangeable, the appellant referred to the different wording used in the patent specification.

Thus, although the claims and paragraph [0129] referred to "partially gelatinized starch", the examples used the term "pre-gelatinized starch". However, on the basis of the disclosure of the entire patent, it is beyond doubt that the pre-gelatinized starch of the examples, read in context, has to be understood to be a partially gelatinized starch. The use of different terms appears to reflect rather the use of sloppy language than the acknowledgement of the equivalence of the terms.

4.1.3 Regarding the prior-art documents cited by the appellant, namely D21 to D34 and D36, they also do not disclose such an equivalence. On the one hand, these documents refer to a pre-gelatinized starch, without

any specific mention of the degree of gelatinization, and merely concern any starch submitted to a gelatinization process; they do not relate to any specific degree of gelatinization. On the other hand, these documents comprise examples of specific starches, known in the art as partially gelatinized starches and falling under the umbrella definition of pre-gelatinized starch. Such examples are "National Starch 1500[®]" (D21, example 19), "Starch 1500[®]" (D22: page 2, left column, lines 7-9; D23: page 6, lines 6-8; D24: page 81, line 6; D25: tables A and B; D26: page 56, line 31-32 and page 57, lines 21-22; D27: page 43, lines 15-16; D28: page 31, lines 20-21; D29: example 1; D30: page 11, line 1; D31: examples 1 and 5; D32: examples 1 and 5; D33: examples 3, 4 and 8; D34: page 9, right column, lines 17-18), "National Starch 1511[®]" (D27: page 43, lines 15-16; D28: page 31, line 20), "Starch 1500LM[®]" (D34: page 9, right column, lines 17-18). There is nothing in these documents which would support the appellant's assertion that the term "pre-gelatinized starch" is equivalent to and thus interchangeable with the term "partially gelatinized starch".

- 4.1.4 In summary, the board agrees with the respondents that the terms "partially gelatinized starch" and "pre-gelatinized starch" are not interchangeable.
- 4.2 The appellant contested the novelty of the subject-matter of claim 1 on the basis of the disclosure of D19, D1, D3, D7 and D8.
- 4.3 The appellant asserted that D19, a document cited under Article 54(3) EPC, disclosed the subject-matter of claim 1 both in the light of its general disclosure and in the light of example 3.

4.3.1 However, the general disclosure of D19 does not disclose the use of a partially gelatinized starch, a water content up to 9% or the use of a softener. Thus the subject-matter of claim 1 is novel over the general disclosure of D19.

4.3.2 As regards example 3, it discloses a chewable, palatable and ductile veterinary composition which comprises:

- 0.0114% of eprinomectin and 4.25% of praziquantel (both being anti-parasitic drugs), corresponding to feature (A) of claim 1;
- 15% artificial beef flavour PC, corresponding to feature (B) of claim 1;
- 20% of propylene glycol, which according to the patent in suit is a softener (see paragraphs [0064] and [0065]) and thus corresponds to feature (D) of claim 1; and
- 8% of water, feature (E) of claim 19.

The composition of Example 3 further comprises:

- 10% of a pre-gelatinized starch from the company Colorcon; and
- 21.719% of corn starch.

In view of what has been said above in point 4.1 about the non-equivalence of the terms "pre-gelatinized starch" and "partially gelatinized starch", the board cannot accept the appellant's argument that the use of

pre-gelatinized starch in example 3 would destroy the novelty of the subject-matter of claim 1.

The board can also not accept the appellant's second argument that the mixture of pre-gelatinized starch and corn starch (not gelatinized at all) used in example 3 would implicitly provide a partially gelatinized starch. The board agrees with the opposition division that the skilled person would understand by partially gelatinized starch one type of starch, a portion of which has been gelatinized, but not a mixture of different types of starch. This is corroborated by D37 which refers to a mixture of corn starch and pre-gelatinized starch as a co-processed starch excipient.

In summary, the subject-matter of claim 1 is novel over D19.

- 4.4 D3 relates to the encapsulation of sensitive components into a matrix to obtain discrete shelf-stable particles. The matrix comprises at least one plasticizable matrix material and a matrix component which is substantially non-plasticizable. The encapsulated product may be incorporated with or without grinding into foods intended for human or animal consumption (column 24, line 40). There is a long list of possible biologically active components (columns 15 to 18).

The plasticizable matrix material may *inter alia* be a biopolymer such as a carbohydrate, such as a modified or pre-gelatinized starch (column 8, line 66 to column 9, line 10). The starch component of the matrices may be substantially ungelatinized or partially gelatinized, and not substantially destructured or dextrinized (column 24, lines 32-34).

The water content of the product is less than about 8% by weight (column 23, lines 38-42).

The appellant has combined different features disclosed in D3 in a mosaic-like fashion to create a combination of features which are not disclosed in combination in D3. There is no direct and unambiguous disclosure of the combination of ingredients specified in claim 1 that lead to a palatable, ductile, chewable composition. Although D3 mentions flavours to improve sensory attributes (column 13, lines 63-67), it does not even mention meat flavourings, which is another indication that D3 is not specifically concerned with veterinary compositions. Moreover, D3 discloses that the products may possess a substantially non-chewable texture, which is perceived as being glassy or fracturable (column 24, lines 10-11), i.e. something which is neither chewable nor ductile as required by claim 1.

In view of the above, the subject-matter of claim 1 is novel over D3.

- 4.5 The orally administered veterinary compositions disclosed in D1, D7 and D8 do not comprise a partially gelatinized starch. There is reference to either a pre-gelatinized starch, with the degree of gelatinization not being disclosed, or a chemically modified/derivatised starch such as sodium starch glycolate or ungelatinized starch such as corn starch and potato starch (D1: paragraphs [0065] and [0080], and example 15; D7: page 19, line 24 to page 20, line 5 and example 2; and D8: paragraphs [0008] to [0010], examples 1-6, and claims 5 and 17). On the basis of

this difference alone, the subject-matter of claim 1 is novel over the disclosure of D1, D7 and D8.

4.6 In conclusion, subject-matter of claim 1 is novel over all cited documents.

5. Inventive step

The patent relates to an easy-to-use, safe, efficacious, and stable veterinary product consisting of a highly palatable, ductile, chewable composition containing an active ingredient against animal pests, pathogens or animal diseases. The pesticidally effective ingredient is dispensed as the animal chews the product (paragraph [0001]). In particular, it deals with an optimized application form of veterinary compositions which allows oral administration of almost each and any active ingredient since it tastes good and is palatable (paragraphs [0012]-[0021]). The combination of the five ingredients in claim 1 allows a product to be formed by cold extrusion, which ensures stability of the active ingredients, even temperature-sensitive ones.

5.1 The closest prior art

5.1.1 The respondents considered D1 to be the closest prior art. It relates to palatable pharmaceutical compositions for oral administration to companion animals (paragraphs [0001]). Thus D1 lies in the same technical field as the patent and also deals with the improvement of the palatability of orally administered pharmaceutical compositions (paragraph [0021]).

The compositions of D1 comprise (a) a pharmaceutically effective amount of a pharmaceutically active

ingredient in combination with (b) a palatability improving agent and (c) a pharmaceutically acceptable carrier (paragraph [0022], claim 1). The desired final composition may be compressed into a tablet or chewable tablet (paragraph [0070]). The active ingredient is a veterinary drug normally given to a companion animal. Paragraph [0056] provides a long list of possible drugs. The palatability-improving agents are non-meat and non-fish derived, but artificial meat flavouring agents are included (paragraphs [0044] and [0050]). Preferably, the water content of the compositions when compressed into tablets is less than about 7.5% (paragraph [0062]). The tablets may comprise *inter alia* a lubricant such as polyethylene glycol (according to the patent a softener) and a disintegrating agent such as corn starch (paragraph [0065]). Example 1 discloses, in particular, the use of pre-gelatinized starch.

5.1.2 Contrary to the assertions of the appellant, none of D3, D7 or D8 can be considered as a more appropriate starting point for the assessment of inventive step:

- D3 deals primarily with the encapsulation of the active ingredient so that it remains stable during further processing, despite the fact that it discloses partially gelatinized starch among other candidates for the plasticizable matrix material of the veterinary pharmaceutical composition. D3 is not concerned with the improvement of the palatability of a pharmaceutical composition. Furthermore, D3 discloses that the products may possess a non-chewable texture (see point 4.4 above).
- D7, although it concerns the improvement of the palatability of veterinary pharmaceutical

compositions (page 2, lines 29-31), does not relate to the stability of the active ingredient, since the extrusion is carried out at 120°C (see the examples). Furthermore, it discloses only gelatinized starch as an ancillary substance of the pharmaceutical composition (page 19, lines 24-26).

- D8, which discloses only gelatinized starch as a component of the veterinary composition (paragraphs [0008] and [0009]), relates to semi-moist orally delivered compositions with a water content up to 20% (claim 1) and does not address the improvement of palatability. Furthermore, it does not concern the stability of the composition during extrusion, since a temperature of 125°F (51.7°C) is disclosed in example 1.

5.1.3 In conclusion, D1 is not only in the same technical field, it also discloses most of the features required by claim 1 and indeed constitutes the closest prior art. D1 does not disclose the combination of the features of claim 1, and in particular not a partially gelatinized starch.

5.2 The technical problem and its solution

5.2.1 As regards the technical problem underlying the invention of claim 1 in view of D1, the respondents saw the problem in the provision of a ductile chewable veterinary composition that can be used with heat-sensitive active ingredients and has (improved) palatability to an animal without adverse effects on stability during extrusion and storage (see paragraphs [0022], [0023], and [0027] to [0030]).

- 5.2.2 The examples of the patent in suit show that the technical problem has indeed been solved by the combination of the features of claim 1. In particular, palatability and stability test were carried out (examples 4 and 5).

At this juncture it may be reiterated that the skilled person, reading the examples in the context of the patent as a whole, would immediately understand that the pre-gelatinized starch used in the examples is a partially pre-gelatinized starch. In fact the respondents had already confirmed in their observations on the opposition (letter dated 15 April 2010) that the pre-gelatinized starch used in the examples of the patent was partially gelatinized Starch 1500[®] from the company Colorcon (D14 and D15).

The stability of the active ingredient during production is due to extrusion at or near room temperature (paragraph [0054]), while its stability during storage is due to the use a softener which keeps the moisture within the composition (paragraph [0131]). The control of the temperature during the whole extrusion process prevents the formation of crunchy or hard products and leads to chewables which are highly palatable and ductile (paragraph [0133]).

- 5.2.3 The appellant asserted that the technical problem was not solved over the entire scope of claim 1, so that the problem to be solved was merely the provision of an alternative composition to D1. Contrary to the disclosure of the patent specification, claim 1 did not contain essential limitations required to obtain the effects sought, namely:

- during extrusion the extruder should be cooled down below room temperature in order to achieve products which were highly palatable and ductile (page 10, lines 24-25 and page 16, lines 46-48);
- the amount of meat flavouring was essential in order to obtain the desired high palatability (page 15, lines 25-27);
- the fat content in the natural meat powder should be 20-55% (w/w) for achieving the desired high palatability, excellent taste and softness of the product (page 15, lines 29-31);
- the artificial meat flavouring was only suitable if it contained 20-55%(w/w) fat (page 15, lines 33-35);
- the partially gelatinized starch had to contain 10-20%(w/w) of pre-gelatinized starch (page 16, lines 22-23);
- the proportion of meat flavouring and partially gelatinized starch was extremely important (page 16, lines 42-43);
- the nature of the softener was important.

5.2.4 It might be true that the specific compositions of the examples provided the best result and that other compositions falling within the scope of claim 1 show less pronounced effects. This, however, does not necessarily mean that they do not solve the technical problem. For example, it is self-evident that the palatability depends on the amount of meat flavouring in the final composition (paragraph [0126]), and thus,

that there is an optimum for every composition. It is, however, the appellant, who bears the burden of proof, and it has not filed any technical evidence showing that the technical problem was not solved over the entire scope of claim 1.

5.2.5 In view of the above, the board accepts that the problem as defined by the respondents is indeed the objective technical problem and concludes that is solved by the features of claim 1.

5.3 Obviousness

5.3.1 Basically, the appellant argued that the compositions of D1 are very similar to the composition of claim 1 and that it would have been obvious to incorporate a partially gelatinized starch into such a composition in order to provide alternative compositions.

5.3.2 The board cannot agree. It is noted that the appellant combined distinct disclosures from various paragraphs in D1 (see above point 5.2.1) in order to maximise the similarity with the claimed composition. However, there is no hint in D1 itself. This illustrates the hindsight selections and combinations that need to be made from the disclosure of D1. To focus on the partially gelatinized starch as the sole distinguishing feature over D1 appears to be an oversimplification of the case.

In fact, D1 itself does not even focus on a ductile, chewable composition. As stated in paragraph [0042], D1 prefers pillable dosage forms that can be crushed or ground by the owner, caregiver, pharmacist or veterinarian so that it can be sprinkled on or mixed with food, dissolved or suspended in liquid, or mixed

with semi-solid food products which can be administered directly or smeared onto the fur for ingestion by the animal during self-grooming. Furthermore, it is stated in paragraph [0032] that the preferred pharmaceutical composition is a tablet, more preferably a hard, compressed, substantially moisture-free tablet. This in fact teaches away from a ductile, chewable composition since such a composition would be unsuitable to being crushed or ground.

- 5.3.3 Thus, faced with the objective technical problem of providing a ductile chewable veterinary composition that can be used with heat-sensitive active ingredients and has (improved) palatability to an animal without any adverse effect on stability during extrusion and storage, the skilled person would have no reason to make the necessary selections from D1. He would also find no hint in the cited prior art to add partially pre-gelatinized starch.
- 5.3.4 As already set out above, D7 and D8 disclose pre-gelatinized starch, i.e. starch with a broader definition than the more specific partially gelatinized starch of claim 1. As D7 and D8 do not directly and unambiguously concern a partially gelatinized starch, the skilled person combining D1 with either D7 or D8 would not arrive at the claimed subject-matter.
- 5.3.5 D3 deals essentially with a method for encapsulating or embedding a solid or liquid component in a plasticizable matrix at a low temperature and under low shear conditions. It does not deal with the issue of improving the palatability of veterinary compositions. Flavours and fragrances are disclosed in D3 as ingredients to be encapsulated by the plasticizable matrix (column 8, lines 50-55) and are used therein as

an alternative to the pharmaceutically active ingredient. Therefore the skilled person would have no reason to consult D3.

But even if he did, he would not find in D3 any motivation to specifically choose a partially gelatinized starch in order to improve palatability. Partially gelatinized starch is disclosed in D3 among other alternatives for the plasticizable matrix but without any particular qualification (column 8, line 66 to column 9, line 20; column 24, lines 32-34); in fact, all examples of D3 use a non-gelatinized starch. Thus the skilled person faced with the problem of improving palatability would have no reason to select from D3 a partially gelatinized starch. Thus he would not combine D1 with D3.

- 5.4 In view of the above, the subject-matter of claim 1 involves an inventive step and claim 1 is patentable.

6. Independent claim 30 relates to a process for the production of a highly palatable ductile chewable veterinary composition of claim 1, and independent claim 33 to the use of components (A) to (E) for the preparation of a highly palatable ductile chewable veterinary composition, i.e. the composition of claim 1. In consequence, their subject-matter is narrower than that of claim 1, and is patentable *mutatis mutandis*.

7. Claims 2-29 correspond to preferred embodiments of claim 1; claims 31 and 32 to preferred embodiments of claim 30; and claims 34 to 60 to preferred embodiments of claim 33. As the independent claims are patentable, the claims dependent on them are patentable *mutatis mutandis*.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the following documents:
 - claims 1 to 60 according to the main request submitted with the letter dated 11 March 2016,
 - description pages 2 to 20 as submitted during the oral proceedings on 26 April 2016.

The Registrar:

The Chairman:



K. Boelicke

W. Sieber

Decision electronically authenticated