Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 27 March 2023

Case Number: T 1577/21 - 3.3.07

Application Number: 13715654.3

Publication Number: 2833866

IPC: A61K9/00, A61K47/12

Language of the proceedings: EN

Title of invention:
SOFT CHEWABLE PHARMACEUTICAL PRODUCTS

Patent Proprietor:
Intervet International B.V.

Opponents:
VIRBAC
CEVA SANTE ANIMALE

Headword:
SOFT CHEWABLE PHARMACEUTICAL PRODUCTS/Intervet International B.V.

Relevant legal provisions:
RPBA 2020 Art. 11, 12
EPC Art. 123(2)

Keyword:
Main request - Admissibility (Yes)
Main request - Amendments (Yes)
Deletion of a proviso
Change of the scope of the claims and Article 123(2) EPC
Remittal to the opposition division

Decisions cited:
G 0002/10, T 1966/16

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1577/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 27 March 2023

Appellant: (Patent Proprietor)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Hertford Road Hoddesdon, Hertfordshire EN11 9BU (GB)
Respondent: (Opponent 1)	VIRBAC 1ère Avenue, 2065m, L.I.D. 06516 Carros (FR)
Representative:	Lavoix 2, place d'Estienne d'Orves 75441 Paris Cedex 09 (FR)
Respondent: (Opponent 2)	CEVA SANTE ANIMALE 10, avenue de la Ballastière 33500 Libourne (FR)
Representative:	Cabinet Becker et Associés 25, rue Louis le Grand 75002 Paris (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 July 2021 revoking European patent No. 2833866 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	J. Lécaillon
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 2 833 866 was granted on the basis of a set of 13 claims.

Independent claim 1 as granted read:

"1. A soft chewable veterinary pharmaceutical product comprising as ingredients,
- sodium pamoate,
- one or more active pharmaceutical ingredients,
- a liquid component,
- a forming agent, and
- optionally one or more excipients."

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the following requests:
- the main request received on 26 March 2021,
- auxiliary request 1 filed as auxiliary request 1b during the oral proceedings of 26 May 2021,
- auxiliary request 2 filed as auxiliary request 4 received on 26 March 2021,
- auxiliary request 3 filed as auxiliary request 1 received on 26 March 2021,
- auxiliary request 4 filed as auxiliary request 1a received on 20 May 2021,
- auxiliary request 5 filed as auxiliary request 2 received on 26 March 2021,

- auxiliary request 6 filed as auxiliary request 3 received on 26 March 2021,
- auxiliary request 7 filed as auxiliary request 5 received on 26 March 2021,
- auxiliary request 8 filed as auxiliary request 5a received on 20 May 2021
- auxiliary request 9 filed as auxiliary request 6 received on 26 March 2021,
- auxiliary request 10 filed as auxiliary request 7 received on 26 March 2021.

IV. The following documents were cited in the opposition proceedings:

D18: P. Zhao et al., Mol. Pharmacol. 78, 560-568, 2010
D19: WO 2011/011235 A1
D20: WO 2002/00603 A1
D22: R. Neubig, Mol. Pharmacol. 78, 558-559, 2010

V. According to the decision under appeal, the main request did not meet the requirements of Article 123(2) EPC in view of the deletion of the feature "pamoic acid or a pharmaceutically acceptable salt thereof, provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient" which was present in original claim 1.

Auxiliary request 1 did not meet the requirements of Article 84 EPC. Auxiliary requests 2-10 did not meet the requirements of Article 123(2) EPC for the same reasons as the main request.

VI. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement of grounds of appeal dated 19 November 2021, the appellant requested, *inter alia*, that the patent be maintained

based on the main request filed with letter dated 25 March 2021 or one of auxiliary requests 1-20, whereby auxiliary requests 3-5 were newly filed, and submitted the following evidence:

D30: "Slow Sodium"
D31: "Sodium Acetate"
D32: CVMP Assessment report for Bravecto

VII. With their respective letters dated 17 March 2022 and 31 March 2022, opponent 01 (hereinafter respondent 01) and opponent 02 (hereinafter respondent 02) requested in particular that auxiliary requests 3-20 and documents D30-D32 not be admitted into the appeal proceedings.

VIII. A communication from the Board, dated 21 November 2022 was sent to the parties, wherein the Board expressed its preliminary opinion that *inter alia* the main request met the requirements of Article 123(2) EPC. The Board also requested a clarification from the appellant regarding the auxiliary requests.

IX. With a letter dated 4 January 2023, the appellant filed a main request and auxiliary requests 1-13. The main request corresponded to the main request submitted in the opposition proceedings on 25 March 2021, wherein claim 1 of the main request was identical to claim 1 as granted.

X. With a letter dated 14 February 2023, respondent 01 informed the parties and the Board that it would not attend the oral proceedings, and requested that the requests filed on 4 January 2023 not be admitted into the appeal proceedings.

XI. With a letter 16 February 2023, respondent 02 also informed the parties and the Board of its non-attendance at the oral proceedings. Respondent 02 maintained all request previously made in the written proceedings.

XII. Given that the Board's decision is in favour of the appellant's main request there was no need to hear the appellant at the oral proceedings, and the oral proceedings were cancelled.

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

Main request - Amendments

The deletion in claim 1 of the proviso "provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient" present in original claim 1 could not extend the subject-matter. It was essential, when deciding on issues of added subject-matter, to identify the technical information that the skilled person, on the date of filing, would have objectively derived from reading the entire original disclosure and not only from the claims. The application as filed directly and unambiguously disclosed sodium pamoate as ingredient of the soft chewable veterinary pharmaceutical product, being a preferred embodiment of “pamoic acid or a pharmaceutically acceptable salt thereof” as compound *per se* for use as an ingredient in the soft chewable veterinary product of the invention, without any indication of its role as active or non-active ingredient (see *e.g.*, page 7, lines 7-16). Moreover, all examples included sodium pamoate, which was further strong support that this compound is preferred as

ingredient of a soft chewable veterinary pharmaceutical product. The term "sodium pamoate" could replace the whole deleted expression in claim 1 as filed including the proviso.

XIV. The arguments of the respondents may be summarised as follows

Main request - Amendments

The removal of the negative characteristic (proviso) "provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient" of the claims was contrary to Article 123(2) EPC, as it changed the scope of the claim 1. Since this feature was no longer present in claim 1, the claimed object was in no way derivable from the content of the application as filed.

Claim 1 of the main request now also covered a soft chewable product comprising not only sodium pamoate but also for example pyrantel pamoate and/or pamoate oxantel. These possibilities were expressly excluded throughout the application filed by the proviso "provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient". Furthermore, several documents D18 to D20 and also D22 had been provided, showing that sodium pamoate was a pharmaceutical active ingredient. Therefore, it was clear that sodium pamoate could not fall within the class of non-active pamoic acid derived ingredients of claim 1 as filed.

XV. Requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained according to the set of claims of the main request or one of auxiliary requests 1-13, all filed with letter of 4 January 2023.

The appellant requested that the case be remitted to the opposition division for further prosecution of the unexamined grounds of opposition, namely novelty, inventive step and sufficiency of disclosure.

Respondents 01 and 02 (opponents 01 and 02) requested that the appeal be dismissed, and that documents D30-D32 not be admitted into the appeal proceedings.

Respondent 01 requested also that the requests filed with letter of 4 January 2023not be admitted into the proceedings and respondent 02 that auxiliary requests 2-4 and 6-13 filed with letter of 4 January 2023, and corresponding to auxiliary requests 3-5 and 8-15 filed with the statement of grounds of appeal, not be admitted.

They also requested that the case be remitted to the opposition division for further prosecution in the event that one of the requests is considered to meet the requirements of Articles 123(2) and 84 EPC.

Reasons for the Decision

1. Admission of the main request into the appeal proceedings

Respondent 01 requests that the requests filed with letter of 4 January 2023, hence including also the main request, not be admitted into the appeal proceedings.

The main request filed on 4 January 2023 corresponds to the main request filed with the statement of grounds of appeal and to the main request on which the decision of the opposition division is based. It was filed again in response to the request for clarification of the requests by the Board. It is therefore not a new request filed in the appeal proceedings and is furthermore a request on which the appeal is based according to Article 12(1)(a) RPBA 2020. For these reasons the main request is part of the appeal proceedings.

2. Main request - Amendments

2.1 Claim 1 of the main request reads:

"1. A soft chewable veterinary pharmaceutical product comprising as ingredients,
- sodium pamoate,
- one or more active pharmaceutical ingredients,
- a liquid component,
- a forming agent, and
- optionally one or more excipients."

2.2 Claims 1, 2 and 5 as originally filed read:

"1. A soft chewable veterinary pharmaceutical product comprising as ingredients,
- pamoic acid or a pharmaceutically acceptable salt thereof, **provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient**,
- one or more active pharmaceutical ingredient,
- a liquid component,
- a forming agent, and
- optionally one or more excipients." (emphasis added)

"2. The product according to claim 1 wherein the product comprises sodium pamoate."

"5. A soft chewable veterinary pharmaceutical product comprising as ingredients,
- a pamoate salt of an active pharmaceutical ingredient, provided that such active pharmaceutical ingredient is not pyrantel pamoate or oxantel pamoate,
- optionally one or more other active pharmaceutical ingredients,
- a liquid component,
- a forming agent,
- optionally pamoic acid or a pharmaceutically acceptable salt thereof, and
- optionally one or more excipients."

2.3 A direct basis for the sodium salt of pamoate is disclosed in original dependent claim 2. Sodium pamoate is also present in all examples and is presented several times as the preferred salt in the description of the application as filed (see page 3, line 11; page 7, lines 10-11 and 21).

2.4 The subject-matter of claim 1 of the main request results from the deletion of the proviso present in

original claim 1. The deletion of a proviso/disclaimer explicitly disclosed in an application as originally filed as "not forming part" of the invention might not be admissible if the deletion results in the "non-part" being still partially claimed or if there is no disclosure in the original application as a whole which renders the remaining claimed subject-matter directly and unambiguously derivable therefrom.

In the present case, claim 1 of the original application makes a distinction between the presence of "*one or more active pharmaceutical ingredients*" and the remaining components of the product, including pamoic acid, even if the original proviso is not taken into consideration. The wording of the term "*one or more active pharmaceutical ingredients*" suggests indeed that the remaining components of the product including pamoic acid or a salt thereof are not considered as active pharmaceutical ingredients.

Moreover, the description discloses the presence of pamoic acid or its salt in the soft chewable veterinary product without specification of its function on page 2, lines 15-20, and all examples according to the claimed invention comprise an active ingredient and sodium pamoate, without specification of the function of the latter. Original independent claim 5, which has a more restricted scope, includes the presence of pamoic acid or its salt, also without any specification of its function.

Finally and importantly, a specific passage on page 7, lines 17-21 of the description states furthermore explicitly that "*In one aspect...and pamoic acid or salts are included in the soft chew composition as an (non-active) ingredient or excipient. Hence the*

composition comprises pamoic acid or salts thereof provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient. ***In one example such pamoic acid or salts is sodium pamoate***" (emphasis added). It appears from this passage on page 7 that the specific sodium pamoate was considered in the application as filed as a non-active ingredient and this passage appears to constitute a direct basis for the omission of the proviso and its replacement by the disclosed equivalent feature and specific compound "sodium pamoate".

2.5 Moreover, the fact that pamoate salts, such as in particular the sodium salt, are presented in some prior art documents as pharmaceutical active ingredients, such as in D18-D20 or D22 as argued by the respondents, is irrelevant to the present case.

First, the teaching of these documents is any case inconsistent with the disclosure of the application as originally filed, even with the presence of the proviso in the claims, since pamoate sodium is not used as an active ingredient in the application as originally filed, while it is clear from the cited documents that it is a potential active ingredient.

Furthermore, this argument appears to be irrelevant for the assessment of the requirements of Article 123(2) EPC, since the relevant question for the purposes of Article 123(2) EPC is whether the amendments remain within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, from the whole of the application as filed (the "gold standard" of G 2/10, OJ 2012, 376). Hence, the concrete basis for the assessment of Article 123(2) EPC is the whole content of the application as filed,

and not contradicting information originating from other documents. Common general knowledge is only used to take in account matter which is implicit to a person skilled in the art from the application as filed, and not to give an interpretation not present in the application as filed.

2.6 According to the opposition division, claim 1 now allows for the presence of a combination of sodium pamoate and a pamoate salt of an active ingredient, while the application as filed discloses only a combination of a pamoate salt of an active ingredient with pamoic acid on page 7, lines 22-23, but not with sodium pamoate. This argument was also brought forward by the respondents, who argue similarly that the product as claimed might now comprise a combination of pamoate sodium with pamoate pyrantel/oxantel which was excluded by the original proviso and which was not disclosed originally, since page 7, lines 22-23 only envisaged a combination of actives with pamoic acid.

In the Board's view, this interpretation is inconsistent with the subject-matter of original claim 1 in combination with claim 2, which encompasses this possible combination . Original claim 1 relates to a product comprising, in addition to pamoic acid, "one or more active pharmaceutical ingredient" without any limitation as to the nature of the active ingredient, which can be a pamoic salt such as pamoate pyrantel/ oxantel, and dependent claim 2 relates to the sodium salt of pamoate; such a combination was therefore implicitly encompassed by the original subject-matter of claims 1 and 2. Moreover, as discussed above, the description on page 7, lines 22-23 provides an explicit basis for such combination, even if this passage relates to pamoic acid, and not specifically to its

salt; the use of a salt of pamoic acid appears indeed to be derivable from the application as filed, since it is repeatedly presented as preferred.

2.7 Another argument of the respondents was that the omission of the proviso in the claims changed the scope of claim 1, resulting that the claimed object was now contrary to Article 123(2) EPC.

The Board also disagrees with this argument. In the Board's view, such criteria relating to the scope of the originally filed claim is inappropriate for the assessment of compliance with Article 123(2) EPC, which refers explicitly to the content of the application as filed, and not to the scope of the claims. The relevant question for the purposes of Article 123(2) EPC is indeed whether the amendments remain within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, **from the whole of the application as filed** (the "gold standard" of G 2/10, OJ 2012, 376). An amendment having the effect of broadening the scope of protection of a claim as originally filed, for instance by generalising it so as to allow the presence of some materials in nature or amounts which were originally excluded from the claim, does not infringe Article 123(2) EPC if the amended subject-matter derives directly and unambiguously from the application as filed as a whole, as it is the case for the present contested patent.

2.8 Consequently, the omission of the proviso "provided that such pamoic acid or pharmaceutically acceptable salt thereof is not an active pharmaceutical ingredient" does not extend beyond the content of the application as filed. The main request meets the requirements of Article 123(2) EPC.

3. Remittal to the opposition division

3.1 All the parties requested that the case be remitted to the opposition division for further prosecution of the unexamined grounds of opposition, namely novelty, inventive step and sufficiency of disclosure in the event that one of the requests is considered to meet the requirements of Articles 123(2) and 84 EPC.

3.2 Under Article 11 RPBA 2020 the Board may remit the case to the department whose decision was appealed if there are special reasons for doing so. In the present case, the main request submitted during the opposition proceedings was found not to meet the requirements of Article 123(2) EPC, and no other substantive issues (such as novelty and inventive step) were dealt with in the decision under appeal.

Under these circumstances, the Board holds that such special reasons are apparent in the present case. As recalled in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of the patent for compliance with the requirements of other grounds of opposition for which no decision of the first instance exists yet. Therefore, the Board considers it appropriate to remit the case to the opposition division (cf Article 111(1) EPC; see also T 1966/16, point 2.2 of the reasons).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairwoman:

B. Atienza Vivancos J. Lécaillon

Decision electronically authenticated