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**Datasheet for the decision
of 27 May 2024**

Case Number: T 1079/22 - 3.3.07

Application Number: 13755420.0

Publication Number: 2819699

IPC: A61K9/10, A61K47/44, A61K47/14,
A61K47/26

Language of the proceedings: EN

Title of invention:
CONTROLLED RELEASE COMPOSITIONS AND THEIR METHODS OF USE

Patent Proprietor:
Elanco New Zealand

Opponent:
Boehringer Ingelheim Animal Health USA Inc.

Headword:
Controlled release/ELANCO

Relevant legal provisions:
EPC Art. 123(2)
RPBA 2020 Art. 12(5)

Keyword:
Amendments - allowable (yes)
Discretion not to admit submission - submission admitted (no)



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Case Number: T 1079/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 27 May 2024

Appellant:
(Patent Proprietor)

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Respondent:
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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 February 2022 concerning maintenance of the
European Patent No. 2819699 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: M. Steendijk
S. Ruhwinkel

Summary of Facts and Submissions

- I. European patent 2 819 699 ("the patent") was granted on the basis of sixteen claims.

Claim 1 as granted related to a composition for intramammary administration including a therapeutically effective amount of an antibiotic and a base configured to provide a controlled release of the at least one active ingredient, the base including colloidal silica, an oil and a surfactant, wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil.

- II. The grant of the patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as filed.

The patent proprietor filed the appeal against the interlocutory decision of the opposition division that the patent as amended in accordance with auxiliary request 1 met the requirements of the EPC.

The decision was based on the main request as filed on 21 September 2020 and auxiliary request 1 filed during the oral proceedings held on 8 October 2021.

Claim 1 of the main request defined:

"A composition for use in treating a microbial infection in an animal wherein the composition is administered by intramammary infusion,

the composition including a therapeutically effective amount of at least one active agent, and a base configured to provide a controlled release of the at least one active ingredient, the base including, an amount of hydrophobic colloidal silica; at least one oil; and at least one surfactant, wherein the active agent is an antibiotic; wherein the viscosity of the composition is below 1000 mPas at a shear rate of 100 1/s and at a temperature of 20°C, and wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil."

The opposition division arrived at the following conclusions:

- (a) The definition of the hydrophobic colloidal silica and the antibiotic being dispersed in the oil in claim 1 of the main request contravened Article 123(2) EPC.
- (b) Claim 1 of auxiliary request 1 defined that the oil and surfactant together form a homogenous oil mixture and that the hydrophobic colloidal silica and the active agent are dispersed in the oil mixture.

Auxiliary request 1 overcame the objection under Article 123(2) EPC.

Auxiliary request 1 also complied with the requirements of sufficiency of disclosure, novelty and inventive step.

- III. With the statement of grounds of appeal the appellant-patent proprietor filed its main request and auxiliary request 1. The main request involved the same set of claims of the main request on which the decision under appeal was based. Auxiliary request 1 corresponded to auxiliary request 1 held allowable in the decision under appeal. With the letter of 3 August 2023 the appellant-patent proprietor filed revised amendments to the description for the main request.
- IV. In the reply to the appeal the respondent-opponent expressly formulated objections under Article 123(2) and 84 EPC against the main request and additionally referred to the documents and submissions filed by all of the parties during the first instance as part of the its case.
- V. In its communication pursuant to Article 15(1) RPBA the Board expressed the preliminary opinion that the respondent's sweeping unspecific references to the submissions during the first instance were not to be admitted under Article 12(5) RPBA and that the description was adequately adapted to the amended claims for the main request. The Board referred in the context of the requirement of Article 123(2) EPC to the possible relevance of the functional restrictions in claim 1 of the main request.
- VI. With the letter of 24 April 2024 the Board was informed that the respondent-opponent would not attend the oral proceedings that had been scheduled for 24 May 2024.
- VII. The Board notified the parties of the cancellation of the oral proceedings in its communication of 26 April 2024.

VIII. The arguments of the appellant-patent proprietor relevant to the present decision are summarized as follows:

The feature in claim 1 of the main request that the hydrophobic colloidal silica and the active agent are dispersed in the oil was directly and unambiguously derivable from the application as originally filed, which referred to the ease of re-dispersion of the disclosed compositions. This indicated that the intended compositions concerned dispersions of the antibiotic and the silica in oil as the vehicle. The method for preparing the compositions described in the application as filed involved the dispersion of the active agent and the colloidal silica to a homogeneous mixture of the oil and the surfactant. The skilled person further recognized that the claim could only relate to compositions in which the surfactant forms a homogenous mixture with the oil in order to function as part of the base of the defined composition.

IX. The arguments of the respondent-opponent relevant to the present decision are summarised as follows:

The feature "wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil" as introduced with respect to claim 1 as originally filed determined a particular constitution of the composition, wherein the silica and the antibiotic are dispersed in the oil without regard to how the surfactant is included in the base. The description of the method of preparing the composition involving the step of mixing the oil and surfactant to form a homogeneous mixture and the references to the ease of re-dispersion of the intended composition in the application as filed only supported particular

embodiments, namely compositions resulting from the dispersion of the antibiotic and the silica in the oil which already included the surfactant or from the re-dispersion of the composition as a whole. The open definition of the composition in claim 1 was not limited to such embodiments and allowed for any form of inclusion of the surfactant in the base, which necessarily affected the resulting constitution of the composition. Claim 1 of the main request therefore represented an impermissible generalisation with respect to the compositions as originally disclosed.

- X. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request.

- XI. The respondent-opponent requested that the appeal be dismissed.

Reasons for the Decision

- 1. Admittance of submissions
 - 1.1 In its reply to the appeal the respondent-opponent expressly specified only the arguments that
 - the main request contravenes Article 123(2) EPC in view of the feature in claim 1 "wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil" (see reply, pages 1-8, section 2.1)

- the main request contravenes Article 84 EPC due to inadequate adaptation of the description to the amended claims (see reply, pages 8-9, section 2.2).

According to the reply to the appeal (see page 1, section 1, see also the footnote 1 on page 1) the respondent-opponent further wished to rely on all the documents and submissions filed by all of the parties during the first instance, which should be considered to be part of the respondent's case with reference to Article 12(2) RPBA.

- 1.2 In its communication pursuant Article 15(1) RPBA the Board pointed out that according to Article 12(3) RPBA the reply shall contain a respondent's complete appeal case and should specify expressly all the requests, facts, objections, arguments and evidence relied on. The Board indicated that the references in the reply to the submissions by the parties during the first instance do not meet the requirement of expressly specifying the arguments relied upon (see Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, V.A.3.2.2).

The Board further indicated that in the decision under appeal the opposition division rejected part of the opponent's arguments for non-compliance of the main request with Article 123(2) EPC and presented reasons for the compliance of auxiliary request 1 with the requirements of sufficiency of disclosure and inventive step which do not appear affected by the difference between the auxiliary request and the main request. The Board expressed the preliminary opinion that under these circumstances the respondent-opponent could and should have expressly specified the arguments intended to be relied upon for its case against the main request

during the appeal proceedings in the reply to the appeal and that the Board therefore intended not to admit the respondent's sweeping unspecific references to the submissions during the first instance (Article 12(5) RPBA).

- 1.3 The respondent-opponent did not submit any substantive arguments in response to the preliminary opinion expressed by the Board in its communication pursuant Article 15(1) RPBA.

The Board therefore confirms its preliminary opinion and accordingly does not admit the respondent-opponent's sweeping references to the submissions by the parties during the first instance proceedings into the appeal proceedings.

2. Main request

- 2.1 Article 123(2) EPC

- 2.1.1 Claim 1 of the application as originally filed defines:

"A composition,
the composition including a therapeutically effective amount of at least one active agent, and
a base including,
an amount of colloidal silica;
at least one oil; and
at least one surfactant,
wherein the viscosity of the composition is below 1000 mPas at a shear rate of 100 1 /s and at a temperature of 20°C."

Claim 1 of the main request more specifically defines the composition for use in treating a microbial

infection in an animal, the base as configured to provide a controlled release of the at least one active ingredient and the active agent as an antibiotic.

Upon appeal the dispute regarding the compliance of the main request with Article 123(2) EPC concerns the additional introduction in claim 1 of the feature:

"wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil".

- 2.1.2 The application as originally filed described the disclosed composition as obtainable by a method involving the preparation of a homogenous mixture of the oil and the surfactant, the dispersion of the active agent, which is the antibiotic, and the subsequent addition of the colloidal silica in this mixture, preferably followed by homogeneously mixing (see pages 16-17, under "Preferred method of manufacture") and referred to the composition being easy to re-disperse (see page 12, line 10; see also page 14, line 6). Accordingly, the application clearly disclosed a composition in which the antibiotic and the colloidal silica are dispersed in an intimate mixture of the oil and the surfactant.

As argued by the respondent-opponent, the feature that the active agent and the silica are dispersed in the oil does not *per se* require that the oil and the surfactant form a homogenous mixture. When considered in isolation, the contested feature could thus for instance allow that the surfactant is included in the composition after the dispersion of the antibiotic and the silica in the oil without further mixing of the ingredients. Such an embodiment would not be covered by the original disclosure of compositions which are re-

dispersed as a whole or which result from dispersion of the antibiotic and the silica in oil already including the surfactant, because in such compositions the hydrophobic colloidal silica and the active agent are dispersed in the oil forming an intimate mixture with the surfactant.

However, claim 1 of the main request defines a composition for use in treating a microbial infection in an animal by intramammary infusion wherein the viscosity of the composition is below the defined value which comprises an antibiotic in a base comprising the oil, the surfactant and the colloidal silica. It is not conceivable for the surfactant be present in such a composition and to serve as part of the base together with the oil and the colloidal silica when it is not in an intimate mixture with the oil.

The Board therefore considers that the definition of the feature "wherein the hydrophobic colloidal silica and the active agent are dispersed in the oil" in claim 1 of the main request does not introduce subject-matter extending beyond the content of the application as originally filed.

The main request does therefore not contravene Article 123(2) EPC.

3. Adaptation of the description

- 3.1 The respondent-opponent objected that the main request contravenes Article 84 EPC due to inadequate adaptation of the description to the amended claims. With the letter of 3 August 2023 the appellant-patent proprietor filed the revised amendments for the main request in response.

3.2 In its communication pursuant Article 15(1) RPBA the Board expressed the preliminary opinion that with these revised amendments the description had been adequately adapted to the amended claims.

The respondent-opponent did not submit any substantive arguments in response to the preliminary opinion expressed by the Board in its communication pursuant Article 15(1) RPBA.

The Board therefore confirms its preliminary opinion and considers that the main request complies with Article 84 EPC.

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 as amended in the following version:

Description:

Paragraphs 2-15, 17, 19-79 and 81-154 of the patent specification

Paragraphs 1, 16, 18 and 80 as filed with the letter of 3 August 2023.

Claims:

No. 1-16 according to the main request as filed with the statement of grounds of appeal

Drawings:

Sheets 1/16-16/16 of the patent specification.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated