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Datasheet for the decision of 22 April 2023

Case Number: T 2292/19 - 3.2.02

Application Number: 10771837.1

Publication Number: 2488145

IPC: A61J1/00

Language of the proceedings: EN

Title of invention:
CONTAINERS FOR COMPOSITIONS COMPRISING MELOXICAM

Applicant:
Boehringer Ingelheim Vetmedica GmbH

Headword:

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 11

Keyword:
Inventive step - (yes)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2292/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 April 2023

Appellant: (Applicant)	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Banse & Steglich Patentanwälte PartmbB Patentanwaltskanzlei Herzog-Heinrich-Straße 23 80336 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 22 March 2019 refusing European patent application No. 10771837.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal is against the examining division's decision refusing European patent application No. 10771837.1. The examining division found that all the requests then on file lacked an inventive step.

II. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with the statement of grounds of appeal or, as an auxiliary measure, that a patent be granted on the basis of one of auxiliary requests 1 to 9, all filed with the statement of grounds of appeal.

In a communication under Rule 100(2) EPC, the board indicated its preliminary opinion that the subject-matter of claim 1 of the main request involved an inventive step and that the board was inclined to remit the case for further prosecution on the basis of the main request.

In a letter dated 31 March 2023 the appellant withdrew its previous request for oral proceedings. The Board then cancelled the oral proceedings.

III. Claim 1 of the main request reads as follows:

1. "A plastic container containing a pharmaceutical composition comprising sodium benzoate and meloxicam or a pharmaceutical acceptable salt thereof, characterised in that the container material is selected from one or more members of the group consisting of a homopolymer of polypropylene (PP), a copolymer of polypropylene (PP), a homopolymer of polyethylene terephthalate (PET)

and a copolymer of polyethylene terephthalate (PET), and optionally one or more non-polymeric components."

IV. The following documents are relevant to this decision:

D1 WO 2009/049304 A1

D8 European Medecines Agency: "Acticam: EPAR - Scientific Discussion", 5 January 2009, retrieved from the Internet: URL:https://www.ema.europa.eu/documents/scientificdiscussion/acticam-epar-scientific-discussion_en.pdf [retrieved on 2019-01-08]

V. The appellant's arguments, where relevant to the decision, can be summarised as follows.

The subject-matter of claim 1 was not rendered obvious by the combination of D8 and D1.

The person skilled in the art starting from D8 and faced with the problem of enhancing the shelf life of the pharmaceutical composition would not have taken D1 into account because D1 related to different compositions used for different applications. The features were only disclosed in D1 in several extensive lists without any specific teaching regarding the compositions and applications in D8.

Even when assuming that the person skilled in the art would have taken D1 into account, D1 taught that the problem of enhancing shelf life was solved by modifying the configuration of the container. D1 did not teach or suggest the solution of claim 1, and in particular it did not teach using a polypropylene (PP) or polyethylene-terephthalate (PET) container material instead of high-density or low-density polyethylene (HDPE/LDPE).

Reasons for the Decision

1. The invention

A container for storing a pharmaceutical composition must be pharmaceutically acceptable, i.e. it cannot interfere with or alter the quality of the pharmaceutical composition. The reverse also applies in that the pharmaceutical compositions should not interfere with the container.

A pharmaceutical composition comprising meloxicam (a non-steroidal anti-inflammatory drug) is frequently used for veterinary medicine, in particular for treating dogs and cats. Sodium benzoate is used as a preservative in oral suspensions of meloxicam which are stored in high-density polyethylene bottles; however, adsorption of sodium benzoate to the wall of these bottles compromises the shelf life of the product and may require an undesirable increased amount of sodium benzoate to account for it, which may cause irritation or allergic reactions.

The invention deals with providing a plastic container which avoids a significant loss of sodium benzoate during storage.

Claim 1 is directed to a plastic container comprising a pharmaceutical composition comprising sodium benzoate and meloxicam or a pharmaceutically acceptable salt of it. The container material is selected from one or more members of the group consisting of a homopolymer of polypropylene (PP), a copolymer of polypropylene (PP), a homopolymer of polyethylene terephthalate (PET) and a

copolymer of polyethylene terephthalate (PET), and optionally one or more non-polymeric components.

2. Inventive step

2.1 According to the appealed decision, the subject-matter of claim 1 of the then main request was not inventive when starting from D8 in combination with D1. Claim 1 of the present main request is broader than claim 1 of the main request considered in the appealed decision in that two features have been deleted from it and placed into dependent claims.

2.2 D8 discloses a 10 ml HDPE/LDPE plastic bottle containing a pharmaceutical composition (Acticam oral suspension) comprising meloxicam and sodium benzoate (see page 1, "Composition of Acticam oral suspension 1.5mg/ml for dogs" and page 2, "Container of Acticam Oral suspension for dogs"). D8 thus provides a valid starting point for the invention in claim 1.

2.3 The subject-matter of claim 1 differs from the disclosure of D8 in that "the container material is selected from one or more members of the group consisting of a homopolymer of polypropylene (PP), a copolymer of polypropylene (PP), a homopolymer of polyethylene terephthalate (PET) and a copolymer of polyethylene terephthalate (PET), and optionally one or more non-polymeric components".

2.4 Page 5, line 29 to page 6, line 4 of the description of the patent application teaches that polypropylene (PP) and polyethylene terephthalate (PET) do not result in any adsorption of the preservative to the wall of the bottle. This leads to increased stability of the

pharmaceutical composition and prolongs its potential shelf life.

2.5 The problem to be solved can thus be considered that of enhancing the shelf life of the pharmaceutical composition.

2.6 D1 deals with unit dose containers for treating various conditions by nebulisation, i.e. by aerosol drug delivery (see abstract and paragraphs [0002] and [0007]).

2.7 D1 mentions both meloxicam (paragraph [0036], line 8) and benzoic acid (paragraph [0043], line 2), but they are separately mentioned within two long lists including many possible active ingredients and excipients/additives (see paragraphs [0030]-[0045]). Hence, the claimed combination of meloxicam and sodium benzoate cannot be regarded as being disclosed in D1 (see decisions dealing with selections from two lists in section I.C.6.2.1.b), Case Law of the Boards of Appeal, 10th edition, July 2022).

2.8 In summary, D1 deals neither with oral suspensions nor with the pharmaceutical composition from D8. It is thus not apparent why the person skilled in the art seeking to enhance the shelf life of the oral suspension in D8 would have consulted D1.

2.9 Even if the person skilled in the art had consulted D1 because improving storage stability of the formulations was mentioned (see paragraphs [0007] and [0008]), D1 does not teach the claimed solution to the problem above.

The solution proposed in D1 involves using containers for holding low volumes of the formulation which have a low internal surface area and a large dispensing end (see paragraphs [0009]-[0010], [0022]-[0026] and [0048]-[0049]).

2.10 D1 discloses a list of container materials for the aerosol formulation (see paragraph [0047] and claim 19). This list comprises polyethylene and in particular low-density polyethylene (LDPE, container material disclosed on page 2 of D8) together with many other materials including polypropylene or polyester; however, D1 does not ascribe an advantage to any of the materials in the list. In particular, D1 does not teach or suggest that polypropylene or polyester would result in an enhanced shelf life as compared with polyethylene.

Hence, even if the person skilled in the art starting from D8 had consulted D1, they would not have been prompted to replace the HDPE/LDPE container composition from D8 with another material composition so as to enhance the shelf life of the pharmaceutical composition.

2.11 It follows that the subject-matter of claim 1 is not rendered obvious by the combination of D8 and D1.

3. Remittal

Pursuant to Article 111(1), second sentence, EPC the board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

Lack of inventive step over the combination of D8 and D1 was the sole reason given in the appealed decision for refusing the patent application. It is not apparent from the file whether or not there were further objections which have not been dealt with in the decision under appeal and which might have prevented a patent from being granted on the basis of the main request. In the board's view, this situation constitutes special reasons within the meaning of Article 11 RPBA 2020 justifying remittal of the case. The appellant did not object to the remittal either.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated