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Datasheet for the decision of 10 September 2020

Case Number: T 0294/16 - 3.3.07

Application Number: 13002434.2

Publication Number: 2662075

IPC: A61K9/16

Language of the proceedings: EN

Title of invention:
Taste masking compositions of praziquantel

Applicant:
Lavet Gyogyszergyarto es Szolgaltato Kft.

Headword:
Taste masking compositions of praziquantel/LAVET.

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 11, 12(2)

Keyword:
Main request - Novelty (Yes)
Remittal to the examining division

Decisions cited:
T 1966/16, T 0547/14, T 0275/15

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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 0294/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 September 2020

Appellant: (Applicant)	Lavet Gyogyszergyarto es Szolgaltato Kft. Otto u. 14. 1161 Budapest (HU)
Representative:	Szentpéteri, Zsolt S.B.G. & K. Patent and Law Offices Andrassy ut 113. 1062 Budapest (HU)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 28 October 2015 refusing European patent application No. 13002434.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	A. Jimenez

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application n°13 002 434.2. The decision was based on the set of claims filed on 11 March 2015.

Claim 1 reads as follows:

"1. A composition which is substantionally *[sic]* free of the bitter taste associated with praziquantel and comprises praziquantel in particulate form coated with a lipid or mixture of lipids which are insoluble in water according to the European Pharmacopoeia in force and which serve to mask the extremely bitter taste of praziquantel upon oral administration but which disperse or dissolve on contact with gastrointestinal fluid."

II. The documents cited during the examination proceedings included the following:

D3: US2006/228399

III. According to the decision under appeal, the subject-matter of at least claims 1-3 was not novel over the prior art D3 which disclosed a taste masked praziquantel particle additionally comprising febantel and pyrantel and a coating comprising lipids. Example 1, Table 1 and Table 2 of D3 revealed that there was at least a fraction of coated particles within the claimed 1-300 micrometer.

IV. The patent applicant (hereinafter the appellant) filed an appeal against said decision. With the statement of

grounds of appeal dated 21 December 2015, he filed a set of 12 claims as main request.

Claim 1 of the request read as follows:

"1. A composition which is substantially free of the bitter taste associated with praziquantel and comprises praziquantel in particulate form coated with a lipid or mixture of lipids which serve to mask the extremely bitter taste of praziquantel upon oral administration but which disperse or dissolve on contact with gastrointestinal fluid.".

V. With the communication sent in preparation for oral proceedings, the Board expressed a preliminary positive view with respect to novelty over D3. The Board also envisaged to issue a decision remitting the case to the examining division for further prosecution, but noted that the appellant requested a patent be granted on the basis of the main request, a request to which the Board did not appear to be able to give right.

VI. In a letter dated 3 August in response to the communication of the Board, the appellant agreed with the intention of the Board and requested the Board to remit the case for further prosecution.

VII. The appellant's written arguments can be summarised as follows:

As regards novelty, D3 did not disclose any kind of coating procedure applied to the particles of praziquantel in order to mask the bitter taste of this drug substance, which was prepared simply by mixing praziquantel with artificial beef flavour and yeast powder, i.e. two flavourings. These masking agents were

mixed with the active ingredient and other conventional, inert ingredients used in producing tablets. The lipids, i.e stearic acid and magnesium stearate, were comprised as lubricants, i.e. as tabletting aids in the formulation, and added in small quantities to tablet formulations to decrease friction at the interface between a tablet's surface and the die wall, just as to prevent sticking to punch faces. By this way, the lipids included in the formulation at a very low concentration of 1 wt% both, had nothing to do with any kind of coating of the praziquantel particles. D3 could not be considered relevant for the present application.

VIII. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution.

Reasons for the Decision

1. Main request - Article 54 EPC

1.1 In its decision the examining division concluded that the subject-matter claimed was not novel over the disclosure of document D3.

1.2 D3 discloses in example 1 and Table 1 the preparation of veterinary tablets comprising 3 wt% praziquantel as active ingredient in combination with febantel and pyrantel pamoate, blended with 20 wt% of artificial beef flavor and 10 wt% of yeast as taste masking agents (see also par. [0026], [0029] of D3), as well as with microcrystalline cellulose, lactose and silicon

dioxide. All the components are mixed in powder form, and finally two lipids, namely 1 wt% of magnesium stearate and 1 wt% of stearic acid, are added to the blender. The finished powder was slugged into tablets, which were ground again and made into tablets in dog bone shapes. Example 2 and Table 2 gives further information as regards the size of ground particulates which are compressed in tablets.

Consequently, D3 does not disclose praziquantel in particulate form coated with a lipid or mixture of lipids, but discloses particulates comprising a mixture of inter alia praziquantel and minor amounts of lipids; having regard to the process of preparation and the respective amounts of praziquantel, lipids and also of the remaining components, in the Board's view there is no reason to assume that said lipids form a coating; there is therefore no disclosure in D3 of praziquantel in particulate form coated with a lipid or mixture of lipids as required by claim 1. The Board agrees furthermore with the appellant that the magnesium stearate and stearic acid are in fact incorporated in the tablets disclosed in D3 as lubricants.

1.3 The claimed subject-matter is therefore novel over D3.

2. Remittal to the examining division

As mentioned above, the subject-matter of present claim 1 is novel. However, the main request has not yet been examined with regard to other requirements of the EPC, such as *inter alia* inventive step, since the decision of the examining division only related to novelty.

Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the

application, or remit the case to the examining division for further prosecution, for examination inter alia of the inventive step.

Since the present appeal was pending on 1 January 2020, the revised version of the RPBA applies (OJ EPO 2019, A63), subject to the transitional provisions set out in Article 25 of said RPBA. In particular Article 11 RPBA 2020 is applicable. Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. The Board holds that such special reasons are apparent in the present case.

The provision of Article 11 RPBA 2020 has indeed to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 1966/16, point 2.2 of the reasons, T 0547/14 points 7.1 and 7.2, and T 0275/15 point 4.). This principle would not be respected if the Board were to conduct a complete examination of the application.

As discussed above, in the present case the examining division decided only on the question of novelty in view of D3 and did not consider the further issues of *inter alia* inventive step and clarity which were mentioned in the communication of the examining division dated 17 November 2014. Under these circumstances, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision is set aside.

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

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated