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Datasheet for the decision of 27 June 2023

Case Number: T 0474/21 - 3.3.04

Application Number: 18178948.8

Publication Number: 3398594

IPC: A61K31/198

Language of the proceedings: EN

Title of invention:
Compositions for improvement of brain function

Applicant:
Grespo AB

Headword:
Alpha-ketoglutarate composition/GRESPO

Relevant legal provisions:
EPC Art. 56
EPC R. 103(1)(a)
RPBA 2020 Art. 13(2)

Keyword:
Amendment after summons - exceptional circumstances (yes)
Inventive step - (yes)

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Case Number: T 0474/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 27 June 2023

Appellant: (Applicant)	Grespo AB Sveavägen 17 14 tr 111 57 Stockholm (SE)
Representative:	Novitas Patent AB P.O. Box 55557 102 04 Stockholm (SE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 24 November 2020 refusing European patent application No. 18178948.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	B. Rutz
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the applicant ("appellant") lies from the decision of the examining division refusing European patent application No. 18 178 948.8 entitled "*Compositions for improvement of brain function*".

II. The examining division decided that the subject-matter of claim 1 of the main request and of auxiliary requests I and II did not extend beyond the content of the application as filed or that of the earlier application (Articles 123(2) and 76(1) EPC). It held that it was novel (Article 54 EPC) but lacked an inventive step (Article 56 EPC) over the disclosure of document D4.

III. With its statement of grounds of appeal, the appellant filed sets of claims of a new main request and of new auxiliary requests 1 and 2, in which claim 1 is identical to claim 1 of the respective claim requests dealt with in the decision under appeal, while the dependent claims contain "*amendments of a 'cleaning up' character*" (see the statement of grounds of appeal, page 1). The main request and auxiliary requests I and II, which had been dealt with in the decision under appeal, were renumbered as auxiliary requests 3 to 5, respectively.

IV. The board summoned to oral proceedings and informed the appellant in a communication under Article 15(1) RPBA of its preliminary opinion regarding some of the issues.

V. With a letter dated 21 February 2023, the appellant filed sets of claims of new auxiliary requests 1 and 3

and renumbered former auxiliary request 1 as auxiliary request 2 and former auxiliary requests 2 to 5 as auxiliary requests 4 to 7.

VI. Oral proceedings before the board took place on 27 June 2023 by videoconference, as requested by the appellant. During the oral proceedings, the appellant withdrew its main request and made auxiliary request 1 filed with its letter dated 21 February 2023 its main request. At the end of the oral proceedings, the chairwoman announced the board's decision.

Claim 1 of the main request reads as follows:

"1. A composition comprising alpha-ketoglutaric acid or a pharmaceutically acceptable salt thereof (AKG), wherein the composition further comprises:
200-20000 USP units of lipase per mmol AKG;
500-50000 USP units of protease per mmol AKG; and
200-20000 USP units of amylase per mmol AKG."

VII. The following documents are cited in the present decision:

D4: US 2011/0064712 A1

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

Main request - claim 1
Inventive step (Article 56 EPC)

The invention according to claim 1 differed from the disclosure of the closest prior art, i.e. D4, in that the claimed composition comprised 200 to 20 000 USP units of lipase, 500 to 50 000 USP units of protease and 200 to 20 000 USP units of amylase per mmol AKG.

The technical effect of this difference was that a therapeutic composition was obtained.

The objective technical problem could be formulated as being the provision of a composition comprising suitable amounts of AKG, lipase, amylase and protease for having a therapeutic effect, e.g. promoting adult neurogenesis.

D4 did not contain any pointers either on its own or in combination with the other cited references to modify the teaching of D4 to thereby arrive at a solution to the objective technical problem within the scope of claim 1 (i.e. the particular combination of ranges of the enzymes). It cannot be assumed that the "enzyme blend" disclosed in D4 had the same (or similar) specific activities (in U/mg) as the enzyme preparations of the present application. The calculations performed by the examining division were therefore not based on established facts and the results were irrelevant. Since D4 disclosed a number of highly complex (and partially undefined) dietary supplements without any experimentally demonstrated effects, there was no basis for assuming that the "enzyme blend" in D4 was of any particular quality, purity or level of specific activity. It was also impossible to reasonably estimate the proportions in which each of the components in the "combination of bromelain, cellulase, amylase, protease, lipase and papain" was present. For instance, the disclosure would quite reasonably allow 99% of the enzyme blend to be cellulase, with only trace amounts of the other enzymes.

It would not have been feasible to arrive at the claimed composition by routine experimentation starting from D4, either. Thus, the solution to the objective technical problem was not obvious and, consequently, the subject-matter of claim 1 involved an inventive step within the meaning of Article 56 EPC.

Request for reimbursement of the appeal fee (Rule 103 EPC)

The line of reasoning put forth by the examining division in items 3.1 to 3.10 as reasons for not acknowledging inventive step was not to be found anywhere in the previous written communications or in the minutes of the oral proceedings. Moreover, this line of reasoning had not been discussed in the oral proceedings before the examining division. That the examining division relied in its refusal on a line of reasoning on which the appellant had not been given an opportunity to comment amounted to a violation of its right to be heard.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request filed as auxiliary request 1 with the letter dated 21 February 2023, or alternatively, on the basis of the claims of auxiliary requests 2 to 7 filed with the same letter. It was further requested that the appeal fee be reimbursed due to a substantial procedural violation.

Reasons for the Decision

Main request
Admission (Article 13(2) RPBA)

1. The claim request was filed after notification of the summons to oral proceedings and thus represents an amendment to the appeal case governed by Article 13(2) RPBA. Besides minor redactional corrections (deletion of redundant claims, adapted dependencies, insertion of "calcium" in claim 11), the claim set differs from that of auxiliary request 3 filed with the statement of grounds of appeal, which was dealt with in the decision under appeal as the main request, in that claim 15 ("for use as a medicament") was deleted. The deletion of claim 15 was the response to an objection with regard to double patenting, which was raised for the first time by the board in its communication under Article 15(1) RPBA. This circumstance was considered exceptional and justified the amendment of the case.

2. The board has therefore admitted the claim request.

Amendments (Article 123(2) EPC and Article 76(1) EPC)

3. The board agrees with the decision under appeal that the amendments do not extend the claimed subject-matter beyond the content of the application as filed or that of the earlier application.

Novelty (Article 54 EPC)

4. The board agrees with the decision under appeal that the subject-matter of the claims is novel.

Inventive step (Article 56 EPC)

5. Claim 1 is directed to a product not limited to any particular use. D4 is considered the closest prior art. It discloses in Example 10 (Table 13) and claim 12 a composition comprising, *inter alia*, L-arginine-alpha-ketoglutarate, a pharmaceutically acceptable salt of alpha-ketoglutaric acid (AKG), and an enzyme blend comprising a combination of bromelain, cellulase, amylase, protease and papain. The difference between the subject-matter of claim 1 and the disclosure of D4 resides in the definition of specific ranges of USP units per mmol AKG for each of the three enzymes, i.e. lipase, protease and amylase.

6. The established difference over D4 (i.e. defined ranges of ratios between AKG and lipase, protease and amylase) results in a synergistic effect as shown in the examples of the application as filed. For one concentration per enzyme falling within the claimed range of ratios with AKG, a synergistic effect was shown (see Examples 1 and 4 and Figures 1, 3, 7 to 9). The ratio between each enzyme and AKG used in these examples is less than 10-fold higher than the lower limit defined in the claim (amylase: 2.6-fold; protease: 7-fold; lipase: 8.8-fold), thus making it credible that the effect is also achieved in the lower end of the ranges. For a higher ratio between each enzyme and AKG a therapeutic effect ("improved cognitive function") was shown for the composition "AKG+enzymes", albeit without a comparison of the

effect of the individual components (Example 5, Figures 10 and 11).

7. In the present case, the ratios in the claim define the matter for which protection is sought in a clear and concise manner. The board therefore considers it credible that the improved synergistic effect explicitly mentioned in the application as filed (see page 13, lines 2 to 13; Examples 1 and 3) is achieved over the whole of the claimed range.

8. The objective technical problem can thus be formulated as being the provision of a composition comprising AKG or a pharmaceutically acceptable salt thereof, lipase, protease and amylase, which has an improved therapeutic effect.

9. D4 does not contain any experimental data testing the disclosed compositions. Moreover, it does not provide any indication as to the relevance and effects of the 24 different components of the composition in Table 13 and claim 12. The skilled person aiming at providing a composition having an improved therapeutic effect was therefore left with the choice of 24 different ingredients in different concentrations without any indication as to which was particularly relevant. Finally, the amounts and activities of the individual components of the enzyme blend is not provided in D4. The skilled person therefore had no indication as to which of the enzymes was relevant and in what amount. In view of this and in the absence of further prior art providing additional teaching in this regard, the subject-matter of claim 1 is not obvious.

10. Claims 2 to 11 are dependent on claim 1 and thus contain all of the features of claim 1.

11. The subject-matter of the claims is inventive (Article 56 EPC).

Request for reimbursement of the appeal fee (Rule 103 EPC)

12. The board takes the view that the examining division did not commit a substantial procedural violation. According to the decision and the minutes of the oral proceedings, the appellant was heard on all of the issues which formed the basis of the decision. The arguments of the examining division with regard to inventive step had also previously been laid out in its communications dated 6 December 2018, 28 March 2019 and 26 September 2019. For example, the examining division stated in its preliminary opinion accompanying the summons to oral proceedings that "*Table 13 discloses that the composition comprises 3000 mg AKG and 200 mg enzyme blend. Thus, the relative amounts of the ingredients appear to be in the same order of magnitude as presently claimed*" and that "*the present composition is considered obvious in view of the closest prior art (D4), which already teaches a composition comprising the present ingredients in amounts, which are very similar (if not in fact novelty anticipating) to the presently specified broadly claimed relative amounts*". Finally, the right to be heard does not imply that the applicant has to be provided with a full reasoning in the preliminary opinion or in oral proceedings prior to a decision of the examining division being pronounced. Given that no substantial procedural violation has occurred, the appeal fee shall not be reimbursed pursuant to Rule 103(1)(a) EPC.

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 with the order to grant a patent with claims 1 to 11 of the main request, filed as auxiliary request 1 with the letter dated 21 February 2023, and a description and drawings to be adapted thereto, as appropriate.

3. The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated