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Datasheet for the decision of 28 June 2010

Case Number: T 1230/05 - 3.3.02

Application Number: 99928759.2

Publication Number: 1087779

IPC: A61K 31/70

Language of the proceedings: EN

Title of invention:
Compositions for increasing energy in vivo

Applicant:
Bioenergy Inc.

Headword:
Increasing energy in vivo/BIOENERGY INC.

Relevant legal provisions:
EPC Art. 123(2), 53(c)

Relevant legal provisions (EPC 1973):
EPC Art. 84, 54(1), 56

Keyword:
"Main request meets the requirements of the EPC: use of ribose for enhancing skeletal muscle performance of normal healthy subjects not disclosed or rendered obvious by the available prior art"

Decisions cited:
-

Catchword:
-

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Case Number: T 1230/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 28 June 2010

Appellant: Bioenergy Inc.
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Ham Lake, MN 55304 (US)

Representative: Lucas, Brian Ronald
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 February 2005 refusing European application No. 99928759.2 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
T. Karamanli

Summary of Facts and Submissions

I. European patent application No. 99 928 759.2 was refused under Article 97(1) EPC 1973 by decision of the examining division posted on 23 February 2005.

II. The decision was based on claims 1-16 of the main request filed with letter of 24 May 2002, claims 1-3 of auxiliary request 1, claims 1-2 of auxiliary request 2 and claims 1-2 of auxiliary request 3, all filed at the oral proceedings on 9 December 2004. The examining division came to the conclusion that the subject-matter of the main request did not meet the requirements of Articles 123(2), 84 and 54 EPC 1973, that the subject-matter of auxiliary request 1 lacked novelty and that the subject-matter of auxiliary requests 2 and 3 lacked inventive step.

III. The appellant (applicant) lodged an appeal against this decision.

IV. With the statement of the grounds of appeal dated 15 June 2005, the appellant filed a new sole request.

V. A summons to oral proceedings was sent on 27 January 2010.

VI. In a communication of 9 March 2010 in accordance with Article 15(1) RPBA, the board raised objections under Articles 123(2) EPC and Article 54 EPC 1973 in connection with claim 1. Moreover, the board had doubts that the subject-matter of independent claims 1 and 3 involved an inventive step.

VII. With a letter of 1 April 2010, the appellant filed amended claims.

VIII. In a telephone conversation on 8 April 2010, the appellant was informed that the board had doubts concerning the requirements of Article 123(2) EPC in connection with the subject-matter of claim 1 filed on 1 April 2010. The appellant clarified that the claims filed on 1 April 2010 replaced the former sole request.

IX. With a letter of 8 April 2010, the appellant filed an auxiliary request.

X. In a further telephone conversation on 14 April 2010, the objections with regard to the main request filed on 1 April 2010 were reiterated. As for the auxiliary request, no objections were raised in connection with claims 1 to 4. However, the subject-matter of dependent claims 5 to 7 was considered not to meet the requirements of Article 123(2) EPC.

XI. With a letter of 20 April 2010, the appellant withdrew all previous requests and filed claims 1 to 4 as new sole request, which correspond to claims 1 to 4 of the former auxiliary request filed with letter of 8 April 2010. The sole independent claim reads as follows:

"1. Use of ribose for enhancing skeletal muscle performance of normal healthy subjects."

XII. By fax of 21 April 2010, the board informed the appellant that the oral proceedings scheduled for 29 April 2010 were cancelled.

XIII. The documents cited during the examination and appeal proceedings included the following:

(1) The Lancet, 340, 507-510 (1992)
(2) Medizin und Ernährung, 11, 59-63 (1970)
(3) Life Sciences, 55, no. 18, 345-349 (1994)
(4) J. Surg. Res., 46, 157-162 (1989)
(5) Ann. Nutr. Metab., 35, 297-302 (1991)
(6) J. Surg. Res., 47, 530-534 (1989)
(7) J. Mol. Cell. Cardiol., 16, 863-866 (1984)
(8) Klin. Wochenschr., 69, 151-155 (1991)
(10) WO 96/18313

XIV. The appellant's submissions can essentially be summarised as follows:

The subject-matter of the claims concerned the administration of ribose to normal healthy subjects engaged in physical activity to enhance skeletal muscle performance. None of the available prior art documents including document (8) suggested any link between ribose, physical activity and improved exercise performance. The object of the study in document (8) was the exercise capacity of an MAD patient and not the performance of the healthy subjects forming the control group.

XV. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the sole request filed with a letter of 20 April 2010.

Reasons for the decision

1. The appeal is admissible.

2. Admissibility of the sole request:

This request was filed at a late stage of the appeal proceedings. However, the amendments made were a reaction to objections raised by the board. As a consequence, the board decided to admit the main request into the proceedings (Article 13 RPBA).

3. Amendments:

Claim 1 is based on page 3, lines 22-23, page 4, lines 1-2 and 6-8 of the application as filed. Claim 2 specifies that the normal healthy subjects of claim 1 are humans. A basis for this can be found on page 1, lines 5-7 as well as in example 2 and figures 2 and 3. A basis for claims 3 and 4 can be found on page 4, lines 6-8.

As a consequence, the requirements of Article 123(2) EPC are met.

4. Exceptions to patentability:

Claim 1 does not include methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body in view of the fact that the use of ribose is limited to normal healthy subjects. Thus, the above-mentioned methods are not claimed so that Article 53(c) EPC does not apply.

5. Clarity:

The term "normal healthy subjects" clearly defines the target group to which ribose is administered as subjects not suffering from any diseases. The requirements of Article 84 EPC 1973 are therefore met.

6. Novelty:

Documents (1), (3), (4), (6) and (7) concern the use of ribose in connection with cardiac diseases. Document (2) describes a study of the influence of various carbohydrates including ribose on disturbed energy metabolism. Document (5) describes the use of ribose for the treatment of patients suffering from myoadenylate deaminase deficiency. In none of these documents is ribose administered to normal healthy subjects.

Document (8) also discloses administration of ribose to a patient suffering from myoadenylate deaminase deficiency. However, this document includes a study comprising a control group of nine healthy men to whom ribose is administered (see Summary of document (8)). However, document (8) is not detrimental to the novelty of present claim 1, as the ribose was not administered in order to enhance skeletal muscle performance of the control group, but simply in order to obtain a reference for the patient suffering from myoadenylate deaminase deficiency, as far as the metabolites serum glucose, plasma free fatty acids, serum lactate, serum ammonia and serum hypoxanthine are concerned (see page 152, Table 1).

As a consequence, the subject-matter of claim 1 and of dependent claims 2 to 4 is novel (Article 54(1) EPC 1973).

7. Inventive step:

Claim 1 of the main request is directed to the use of ribose for enhancing skeletal muscle performance of normal healthy subjects.

As regards the definition of the closest prior art, the board concludes that, in view of the fact that the claimed use concerns non-therapeutic enhancement of skeletal muscle performance, documents (1) to (7), which are directed to the use of ribose for treating pathological conditions, do not qualify as closest prior art.

Document (8) also concerns the use of ribose in the treatment of a disease, i.e. myoadenylate deaminase deficiency. However, as was already mentioned in point 6 above, this document includes a study comprising a control group of nine healthy men to whom ribose was administered. This study reveals that intake of ribose results in a higher increase in plasma lactate concentration after 30 minutes of exercise in the healthy subjects (see page 153, last three full paragraphs on the right hand column). A possible explanation for this increase is that ribose is degraded to lactate via the pentose-phosphate pathway in the muscle cell, which provides the cells with additional ATP (see paragraph bridging pages 153 and 154) and thus with additional energy.

However, a closer look at the experimental conditions shows that the tests were carried out after an overnight fast which the MAD patient and the control subjects were required to undertake (see first complete paragraph of the left-hand column on page 152) so that an undue accumulation of ADP and AMP in the MAD patient and a consequent decrease in the energy yield from ATP leading to muscle cramps could be avoided. For the normal subjects the selected level of exercise was arbitrary and of no significance. All this test shows is that giving a carbohydrate, in this case ribose, as energy source to starved subjects provides cellular ATP by degradation of ribose to lactate via the pentose-phosphate pathway. The same effect would have been obtained by using another carbohydrate such as glucose. This test has, however, no relevance for healthy subjects in their normal state. As a consequence, document (8) is not pertinent for inventive step, either.

The board is of the opinion that document (10) constitutes the closest prior art. Document (10) relates to avoiding or delaying the onset of muscular fatigue with athletes and enhancing their muscular performance by administering creatine and a carbohydrate such as glucose (see page 9, lines 1-4 and 12-14); examples 1-4; claims 1-7).

As a consequence, the technical problem underlying the present application can be seen in the provision of a further method for enhancing skeletal muscle performance of normal healthy subjects. The problem was solved by the method as claimed in claim 1, i.e. by

using ribose as active agent. In view of the results described in example 2 of the present application, the board is convinced that the problem was plausibly solved.

In view of the fact that there are no indications in the available prior art that ribose is capable of enhancing skeletal muscle performance in normal healthy subjects, the skilled person had no reason to replace creatine and glucose, which are the active agents of document (10), with ribose. As a consequence, the subject-matter of claim 1 and of dependent claims 2 to 4 involves an inventive step (Article 56 EPC 1973).

8. In view of the above, the appellant's sole is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent with the following claims and a description to be adapted: claims 1 to 4, filed with the letter of 20 April 2010.

The Registrar: The Chairman

N. Maslin U. Oswald