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Datasheet for the decision of 18 January 2010

Case Number: T 1151/05 - 3.3.02

Application Number: 01122563.8

Publication Number: 1188437

IPC: A61K 31/19

Language of the proceedings: EN

Title of invention:
Beta-hydroxybutyric acid or acetoacetic acid or salts or esters therof for use in improving cerebral function

Applicant:
BTG INTERNATIONAL LIMITED

Opponent:
-

Headword:
β-Hydroxybutyric acid/BTG INTERNATIONAL LIMITED

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 76(1)

Keyword:
"All requests: Article 76(1) - (no): no basis for the amendments in the parent application"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1151/05 **-** 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 18 January 2010

Appellant: BTG INTERNATIONAL LIMITED
10 Fleet Place
Limeburner Lane
London EC4M 7SB (GB)

Representative: Hiebl, Inge Elisabeth
Kraus & Weisert
Patent- und Rechtsanwälte
Thomas-Wimmer-Ring 15
D-80539 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 20 April 2005 refusing European application No. 01122563.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

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

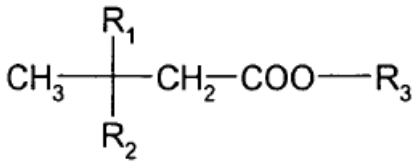
Summary of Facts and Submissions

I. European patent application No. 01 122 563.8, which is a divisional application of European patent application No. 96 118 764.8, was refused by a decision of the examining division of 7 April 2005 on the basis of Article 97(1) EPC 1973 on the grounds that the subject-matter of the main and sole request lacked clarity, support and sufficiency as well as novelty and an inventive step. Moreover, the requirements of Article 123(2) EPC were not met either.

II. The decision was based on claims 1-6 of the main request filed with letter of 25 June 2004.

Independent claim 1 of the main request before the examining division reads as follows:

"1. Use of a compound represented by the following formula (1)



(I)

wherein R_2 represents a hydrogen atom when R_1 is a hydroxyl group;
or R_1 and R_2 are combined together to form an oxo group;
R_3 represents a hydrogen atom, an alkali metal, or a monohydric, dihydric or trihydric alcohol residue, which may be an oligomer of 2-10 molecules of ß-hydroxybutyric acid when R_1 represents a hydroxyl

group and R_2 and R_3 represent hydrogen atoms, for the manufacture of a medicament for protecting cerebral mitochondria in patients suffering from impaired cerebral metabolism, other than that occurring with edema or cerebral infarct."

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

(1) Can. J. Physiol. Pharmacol., vol. 71, no. 7, 465-472 (1993)

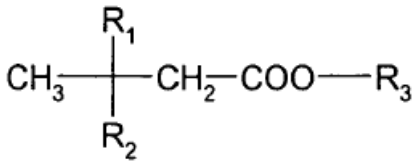
IV. The arguments in the first instance decision may be summarised as follows:

As regards clarity, support by the description and sufficiency, the application failed to identify any therapeutic indications falling within the scope of the claims. Moreover, the subject-matter of claim 1, to the extent it could be understood, lacked novelty over document (1). In addition, the requirements of Article 123(2) EPC were not met because of an insufficient disclaimer introduced into claim 1.

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

VI. With the statement of the grounds of appeal dated 19 August 2005, the appellant filed a new sole request. The sole independent claim reads as follows:

"1. Use of a compound represented by the following formula (1)



(I)

wherein R_2 represents a hydrogen atom when R_1 is a hydroxyl group;
or R_1 and R_2 are combined together to form an oxo group;
R_3 represents a hydrogen atom, an alkali metal, or a monohydric, dihydric or trihydric alcohol residue, which may be an oligomer of 2-10 molecules of ß-hydroxybutyric acid when R_1 represents a hydroxyl group and R_2 and R_3 represent hydrogen atoms, for the manufacture of a medicament for protecting cerebral mitochondria in patients suffering from impaired cerebral metabolism due to cerebral ATP depletion."

VII. With letter of 14 September 2005, the appellant filed further evidence for demonstrating that the term "mitochondrial diseases" is commonly used in the art.

VIII. Summons to oral proceedings were sent on 15 October 2009.

IX. In his reply of 9 December 2009, the appellant withdrew his request for oral proceedings and requested a decision according to the state of the file. Moreover, an auxiliary request, henceforth named auxiliary request I, was submitted. Claim 1 reads as follows:

"1. Use of a compound selected from ß-hydroxybutyric acid, sodium ß—hydroxybutyrate and esters of ß-hydroxybutyric acid for the manufacture of a medicament for protecting cerebral mitochondrial function against the effects of reduced oxygen supply to the electron transport system."

X. In its communication dated 21 December 2009, the board raised objections under Article 76 EPC 1973 in connection with claim 1 of the main request and claim 1 of auxiliary request I.

XI. With letter of 8 January 2010, the appellant filed auxiliary request II. The withdrawal of the request for oral proceedings was reiterated. The sole independent claim of auxiliary request II reads as follows:

"1. Use of a compound selected from ß-hydroxybutyric acid, sodium ß-hydroxybutyrate and esters of ß-hydroxybutyric acid for the manufacture of a medicament for protecting against cytotoxicity caused by blocking ATP production through the inhibition of cerebral mitochondrial cytochrome oxidase."

XII. With the fax of 13 January 2010, the board informed the appellant that the oral proceedings scheduled for 18 January 2010 would take place.

XIII. With the fax of 15 January 2010, the appellant informed the board that he would not be present at the oral proceedings. A decision according to the state of the file was requested.

XIV. Oral proceedings were held on 18 January 2010 in the absence of the duly summoned appellant in accordance with Rule 115 EPC and Article 15(3) RPBA.

XV. The appellant's submissions in connection with the requirements of Article 76 EPC 1973 can essentially be summarised as follows:

No submissions were made with respect to the main request and auxiliary request I. As regards auxiliary request II, reference was made to page 3 and to page 6, lines 2-10 of the parent application. Page 6 specified in lines 2-4 that KCN exerted its cytotoxicity by reducing the oxygen supply to the electron transport system and thus by blocking ATP production through the inhibition of mitochondrial cytochrome oxidase. The cytotoxic effect of KCN was delayed by continuous intravenous infusion of ß-hydroxybutyric acid, which exerted its effect by promoting cerebral ATP production and accumulation.

XVI. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request filed with the statement of grounds of appeal, or in the alternative, according to the auxiliary request I filed with letter of 9 December 2009 or to the auxiliary request II filed with letter of 8 January 2010.

Reasons for the decision

1. The appeal is admissible.

2. Admissibility of the auxiliary requests:

2.1. Auxiliary request I:

Auxiliary request I was filed with letter of 9 December 2009, i.e. at a late stage of the appeal proceedings. However, in view of the fact that the amendments made were of a simple nature and clearly intended to improve the appellant's position with regard to the grounds of refusal, the board admitted auxiliary request I into the proceedings (Article 13(1) RPBA).

2.2. Auxiliary request II:

Although filed at a very late stage of the appeal proceedings, auxiliary request II is admissible (Article 13(1) RPBA), since it is a fair attempt to overcome the objections raised in the board's communication of 21 December 2009.

3. Basis in the parent application as filed:

3.1. Main request:

Claim 1 of the main request is directed to the use of a compound according to formula (1) for the manufacture of a medicament for protecting cerebral mitochondria in patients suffering from impaired cerebral metabolism due to cerebral ATP depletion.

As was already mentioned in the official communication of 21 December 2009, there is no basis for the claimed use in the parent application, in particular as far as the feature "suffering from impaired cerebral metabolism **due to cerebral ATP depletion** " is concerned [emphasis added by the board]. As a consequence, the requirements of Article 76(1) EPC 1973 are not met.

3.2. Auxiliary request I:

Claim 1 of auxiliary request I is directed to the use of ß-hydroxybutyric acid or certain derivatives thereof for the manufacture of a medicament for protecting cerebral mitochondrial function against the effects of reduced oxygen supply to the electron transport system.

As was already mentioned in the official communication of 21 December 2009, there is no basis in the parent application for the feature "for protecting cerebral mitochondrial function against the effects of reduced oxygen supply to the electron transport system". The passage on page 6, lines 2-4 states that "KCN **is believed** to show cytotoxicity by reducing the oxygen supply to the electron transport system and blocking ATP production through the inhibition of mitochondrial cytochrome oxidase" [emphasis added by the board]. It is noted that this statement describes the mechanism of the toxic effects of KCN rather than a property of ß-hydroxybutyric acid. However, by taking into consideration that "KCN-induced death was delayed by continuous intravenous infusion of ß-hydroxybutyric acid" and that "ß-hydroxybutyric acid, the blood level of which probably increased during continuous infusion,

may have exerted this effect by promoting cerebral ATP production and accumulation" (see page 6, lines 7-10) [emphasis added by the board], one could by additionally including the passage on page 3, lines 3-4 and by accepting the speculative statements (see the bold passages above) as a valid disclosure construe a basis in the parent application for the use of ß-hydroxybutyric acid for the manufacture of a medicament for protecting cerebral mitochondrial function against the effects of reduced oxygen supply to the electron transport system and blocked ATP production through the inhibition of mitochondrial cytochrome oxidase by continuous intravenous infusion. However, even in that case, the requirements of Article 76(1) EPC 1973 are not met, as, compared to the disclosure described above, the subject-matter of present claim 1 is subject to the following unallowable generalisations:

a) the effects against which protection should be achieved are generalised from "reduced oxygen supply to the electron transport system and blocked ATP production through the inhibition of mitochondrial cytochrome oxidase" to only "reduced oxygen supply to the electron transport system" for which there is no basis in the parent application.

b) the administration by means of continuous infusion was generalised to any administration, for which there is no basis in the parent application, as the relevant passage on page 6 (see lines 8-13) clearly indicates that the protection of mitochondrial function requires continuous infusion, which effects an increase of the ß-hydroxybutyric acid blood level.

Therefore, the requirements of Article 76(1) EPC 1973 are not met.

3.3. Auxiliary request II:

Claim 1 of auxiliary request II is directed to the use of ß-hydroxybutyric acid or certain derivatives thereof for the manufacture of a medicament for protecting against cytotoxicity caused by blocking ATP production through the inhibition of cerebral mitochondrial cytochrome oxidase.

The feature "cytotoxicity caused by blocking ATP production through the inhibition of cerebral mitochondrial cytochrome oxidase" is also disclosed on page 6 of the parent application (see lines 3-4), but as was already explained in point 3.2 above, only as a description of the mechanism of the toxic effects of KCN and not as a property of ß-hydroxybutyric acid and only in combination with the reduction of the oxygen supply to the electron transport system. Therefore, the reasoning developed in point 3.2 above in connection with claim 1 of auxiliary request I applies ***mutatis mutandis*** to claim 1 of auxiliary request II: again two generalisations have to be made from the subject-matter defined by the passages on page 6, lines 2-10 and page 3, lines 3-4. This time the effects against which protection should be achieved (generalisation (a) in point 3.2. above) are generalised from "reduced oxygen supply to the electron transport system and blocked ATP production through the inhibition of mitochondrial cytochrome oxidase" to only "blocked ATP production through the inhibition of mitochondrial cytochrome

oxidase", for which there is no basis in the parent application. As for the generalisation of the administration, see generalisation (b) in point 3.2 above.

As a consequence, the subject-matter of claim 1 of auxiliary request II does not meet the requirements of Article 76(1) EPC 1973.

4. As the relevant passages in the parent application mentioned in 3.2 and 3.3 above are identical in the divisional application as originally filed (see page 3, lines 3-5 and page 6, lines 2-10 of the divisional application as originally filed), the objections raised in points 3.2 and 3.3 above are also valid under Article 123(2) EPC in connection with the divisional application as originally filed.

5. In view of the above finding, a further evaluation concerning the grounds of refusal is not necessary.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman

N. Maslin U. Oswald