Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 12 June 2015

Case Number: T 0714/13 - 3.3.02

Application Number: 01958837.5

Publication Number: 1399150

IPC: A61K31/34, A61K31/35

Language of the proceedings: EN

Title of invention:
VITAMIN C COMPOSITIONS

Applicant:
The Ester C Company

Headword:
Compositions comprising vitamin C and a secondary compound / Ester C

Relevant legal provisions:
EPC 2000 Art. 52(1), 53(c), 54(2), 54(5), 84, 111(1), 114(2), 123(2)
EPC 2000 R. 115(2)
RPBA Art. 13, 15(3)

Keyword:
Oral proceedings - held in absence of appellant
Admissibiliy of main request and first auxiliary request (yes)
- Bona fide attempt to remedy newly raised objections
Admissibility of second auxiliary request (no) -
not clearly allowable;
Main request and first auxiliary request: purpose-limited product claim (no) -
no medical treatment, novelty (no);
Third and fourth auxiliary requests: amendments -
added subject-matter (yes)

Decisions cited:
T 0290/86, G 0001/83, G 0005/83, G 0006/83, G 0004/92, G 0010/93, G 0002/08

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0714/13 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 12 June 2015

Appellant: (Applicant)	The Ester C Company 6735 Inter-Cal Way Prescott AZ 86301 (US)
Representative:	Bates, Philip Ian Reddie & Grose LLP 16 Theobalds Road London WC1X 8PL (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 18 October 2012 refusing European patent application No. 01958837.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	M. C. Ortega Plaza
	L. Bühler

Summary of Facts and Submissions

I. European patent application No. 01958837.5, based on international application PCT/US01/20431 published as WO 03/002113, was filed with four claims.

II. The following document was cited *inter alia* during the examination and appeal proceedings:

D2: US 6,197,813 B1

III. The present appeal lies from the decision of the examining division refusing the patent application under Article 97(2) EPC for lack of inventive step (Article 56 EPC) of the main request filed with letter dated 3 July 2012, representing the sole request before the examining division.

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

"1. A composition for use in the induction of selective apoptosis of human tumor cell-types comprising:
a vitamin C compound; and
at least one secondary compound selected from the group consisting of 4-hydroxy-5-methyl-3(2H)-furanone and 3-hydroxy-kojic acidwherein *[sic]* the amount of secondary compound is from 0.01 to 1.0% by weight of the total composition."

IV. The appellant (applicant) lodged an appeal against said decision and filed grounds of appeal. With its grounds of appeal it filed a main request (identical to the set of claims serving as the basis for the examining division's decision) and a first, second and third

auxiliary request (together with an adapted description).

V. The board issued a communication pursuant to Rule 100(2) EPC and Article 17(1) of the Rules of Procedure of the Boards of Appeal (RPBA).

In said communication the board pointed out that following the principles set out in Enlarged Board of Appeal decision G 10/93, OJ EPO, 1995, 172, it had the power to examine whether the application or the invention to which it related met the requirements of the EPC, including requirements which the examining division had not taken into consideration.
The board in its communication made *inter alia* a thorough analysis of the construction of claim 1 of the main request, indicating that the purpose stated in the claim 1 "*for use in the induction of selective apoptosis of human tumor cell-types*" related merely to a technical effect but not to any method of treatment as required by Articles 54(5) and 53(c) EPC 2000.
Consequently, in the board's view claim 1 of the main request related to a product "*per se*" claim which was not restricted, except as regards the suitability, by the stated use.
The board also raised an objection of lack of support in view of the component defined in claim 1 as "a vitamin C compound".
Furthermore, the board made some observations on the novelty of the subject-matter claimed vis-à-vis document D2.
Beyond that it pointed out that the second and third auxiliary requests (renumbered later by the appellant as third and fourth auxiliary requests) contravened the requirements of Article 123(2) EPC since they related

to an unallowable generalisation from the products A and B in example 1.
Finally, the board indicated that the admissibility of any request filed after its communication would have to be considered under Rule 137 EPC and Articles 12 and 13 RPBA.

VI. In reply to the board's communication the appellant submitted with letter of 30 September 2013 a new main request and first to fourth auxiliary requests. The third and fourth auxiliary requests are identical to the second and third auxiliary requests filed with the grounds of appeal.

Claim 1 of the main request reads as follows:

"1. A composition for use in the induction of selective apoptosis of human tumor cell-types comprising:
a **mineral ascorbate**; and
a secondary compound selected from the group consisting of 4-hydroxy-5-methyl-3(2H)furanone and 3-hydroxy-kojic acid, wherein the amount of secondary compound is from 0.01 to 1.0% by weight of the total composition." (emphasis added)

Claim 1 of the first auxiliary request derives from claim 1 of the main request, with the amount of the secondary compound defined as **"up to 1.0% by weight of the total composition"** (emphasis added).

Claim 1 of the second auxiliary request reads as follows:

"1. A composition comprising: calcium ascorbate; and 4-hydroxy-5-methyl-3(2H)-furanone, wherein the amount of calcium ascorbate is 95% by weight of the total

composition, and the amount of 4-hydroxy-5-methyl-3(2H)-furanone is 1% by weight of the total composition."

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that mineral ascorbate is replaced by **"a vitamin C compound"** and in that the amount of secondary compound is **"from 0.2 to 1.0% by weight"** of the total composition (emphasis added).

Claim 1 of the fourth auxiliary request reads as follows:

"1. A composition for use in the induction of selective apoptosis of human tumor cell types comprising:
a vitamin C compound; and
at least one secondary compound selected from the group consisting of 4-hydroxy-5-methyl-3(2H)-furanone and 3-hydroxy-kojic acid,# *[sic]*
wherein said secondary compound is 4-hydroxy-5-methyl-3(2H)-furanone in an amount of 1.0% by weight of the total composition; or
wherein said secondary compound is 3-hydroxy-kojic acid in an amount of 0.2% by weight of the total composition."

VII. Oral proceedings took place on 12 June 2015 in the absence of the appellant, who had been duly summoned but had informed the board by *epoline* on 13 May 2015 that it would not be attending the oral proceedings.

VIII. The appellant's written arguments submitted during the appeal proceedings may be summarised as follows:

Admissibility

The main request and first and second auxiliary requests should be admitted into the proceedings as they had been filed as a direct response to the board's communication and the subject-matter of these new requests did not diverge and was clearly allowable in the sense that they did not open new issues.

Claim construction

The technical feature of claim 1 of the main request "*for use in the induction of selective apoptosis of human tumor cell-types*" related to a method of treatment as required by Articles 54(5) and 53(c) EPC 2000. It was readily apparent to the person skilled in the art having regard to his common general knowledge, that selective apoptosis of human tumour cell-types led to the destruction of tumour cells, and thus to an effective treatment of tumour. Hence, this was not a mere technical effect but represented a technical feature of the claim, and whether it could be obtained *in vitro* was irrelevant. Further, it was disclosed on page 1 of the application that the invention was intended for medical use. Consequently, the claimed use was limiting the scope of claim 1 also in view of decision T 290/86 (OJ EPO 1992, 414), which found that medical-use claims can be based on a new technical effect.

Clarity

The phrase "vitamin C compound" had been replaced by "mineral ascorbate" in claim 1 of the main request and first auxiliary request, and by "calcium ascorbate" in claim 1 of the second auxiliary request, in order to overcome the objection of lack of support under Article 84 EPC.

Novelty
The subject-matter of claim 1 of the main request and first, third and fourth auxiliary requests was novel over document D2 because document D2 did not disclose a composition for use in the induction of selective apoptosis of human tumour cell-types. The subject-matter of claims 1 and 2 of the second auxiliary request was novel over document D2 since document D2 did not disclose a composition comprising calcium ascorbate or sodium ascorbate and the specific second component in the amounts as claimed.

Amendments and support
Products A and B of example 1 of the application as originally filed provided support within the meaning of Articles 84 and 123(2) EPC and disclosure within the meaning of Article 83 EPC for the subject-matter of the second, third and fourth auxiliary requests.

IX. From the written submissions, the board establishes that the appellant's requests are as follows:

The appellant (applicant) requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, of one of the first to fourth auxiliary requests, all filed with letter dated 30 September 2013.

The appellant further requested remittal to the department of first instance.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the appellant, who had been duly summoned but had decided not to attend.

If a party duly summoned to oral proceedings before the European Patent Office does not appear as summoned, the proceedings may continue pursuant to Rule 115(2) EPC without that party.

The present decision is based on facts and evidence presented in the written proceedings and on which the appellant had an opportunity to comment. The conditions set forth in Enlarged Board of Appeal decision G 4/92 (OJ EPO 1994, 149) are therefore met.

Moreover, as stipulated by Article 15(3) RPBA, the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

3. Request for remittal

Having regard to the appellant's request for grant of a patent, the request for remittal was to be understood as requesting the board to conclude the substantive examination and establish the text for grant and to remit the case for completion of the remaining formalities (filing of translations, payment of fees and publishing). In view of the outcome of the appeal such request could not be allowed.

Should the appellant have requested remittal for further examination, by the department of first instance, of issues or requests considered for the

first time on appeal, Article 111(1) EPC establishes no absolute right for the party to have all matters raised in appeal proceedings examined by two successive instances; on the contrary, it leaves it to the board of appeal to decide, in the light of the circumstances of the case, whether or not to remit it to the department of first instance.

In the present case, the board exercised its power under Article 111(1) EPC to fully examine the subject-matter claimed in the sets of claims admitted into the proceedings and declined not to remit the case since there was no single request, which could be found allowable.

4. Admissibility of the main request and first and second auxiliary requests

4.1 The main request and first auxiliary request were filed as a direct reaction to the objection under Article 84 EPC raised in the board's communication expressing the board's preliminary opinion.

They differ from the main request and first auxiliary request filed with the grounds of appeal in that the feature "vitamin C compound" is replaced by "mineral ascorbate" and the expression "at least one" before secondary compound is replaced by "a".

These amendments are straightforward, simple, easy to be dealt with and do not raise new issues.

The board therefore exercised its discretion pursuant to Article 13 RPBA in conjunction with Article 114(2) EPC and admitted the main request and the first auxiliary request into the proceedings.

4.2 The second auxiliary request was filed with the response to the board's communication dated 1 August 2013.

Claim 1 of the second auxiliary request is *prima facie* not allowable (Article 123(2) EPC) since the definition of the composition relates to an unallowable generalisation of product A in example 1 of the application as originally filed, in view of the fact that the other components, in particular ascorbic acid and dehydroascorbic acid, present in 4 wt% in Product A, are not defined in the claim.

Given the fact that the board had already indicated with its communication that the subject-matter of the second and third auxiliary requests (renumbered as third and fourth auxiliary requests) contravened the requirements of Article 123(2) EPC since they related to unallowable generalisations from products A and B in example 1, it would be inconsistent with procedural economy to admit a further auxiliary request, which *prima facie* contravenes Article 123(2) EPC for analogous reasons, namely those concerning an unallowable generalisation of example 1.

Therefore, taking into account the provisions of Article 13 RPBA, in particular the current state of the proceedings and the need for procedural economy, and exercising its discretion, the board did not admit the second auxiliary request into the proceedings.

5. Main request

5.1 Claim construction

5.1.1 The subject-matter of claim 1 of the main request relates to

i) a composition for use in the induction of selective apoptosis of human tumour cell types comprising
ii) a mineral ascorbate; and
iii) a secondary compound selected from the group consisting of 4-hydroxy-5-methyl-3(2H)furanone and 3-hydroxy-kojic acid,
iv) wherein the amount of secondary compound is from 0.01 to 1.0% by weight of the total composition.

5.1.2 EPC 2000 allows purpose-related product claims for any substance or composition comprised in the state of the art for **any specific use** in a method referred to in Article 53(c) EPC 2000, provided that it is not comprised in the state of the art (Article 54(5) EPC 2000). The methods mentioned in Article 53(c) EPC 2000 are **methods for treatment of the human or animal body** by surgery or therapy and diagnostic methods practised on the human or animal body (emphasis added).

5.1.3 Hence, what needs to be assessed is whether the purpose-related claim 1 is in fact a claim for a product which is **limited by the medical treatment in which it has to be used.**

5.1.4 The wording of claim 1 of the main request does not require that the technical effect is achieved only in and for a medical treatment under Article 53(c) EPC 2000. The purpose stated in feature i) of claim 1 "for use in the induction of selective apoptosis of human tumor cell-types" does not mention **any method of treatment as required by Articles 54(5) and 53(c) EPC**

2000, but merely relates to a technical effect which may also be attained *in vitro*.

5.1.5 Moreover, according to Article 84 EPC the claims shall define the matter for which protection is sought and they shall be clear, concise and supported by the description.

The **only** passage in the application as originally filed concerning the technical effect stated in claim 1 appears on page 2, second paragraph:

"In addition to the normal utility of the Vitamin C component, these compositions will induce improved dose-dependent, selective apoptosis of diverse human tumor cell-types, even though the concentration of the secondary component in these compositions is very low, i.e., from about .01 to about 1.0% by weight of the total composition".

There is, however, no mention in the application as filed as to which are the tumour cell-types which undergo apoptosis, nor are any data displayed concerning the tumour cytotoxic activity of the compositions claimed. Moreover, in the whole description there is no single test method or assay mentioned, which could have served as a valid model for supporting a claim directed to a purpose-related product for use in a medical treatment against tumours.

Hence, the application as originally filed does not provide a basis for claiming a composition for use in the treatment of cancer. Furthermore, even taking into account the whole content of the application as filed, there is a lack of support for considering the purpose stated in feature i) of claim 1 "for use in the

induction of selective apoptosis of human tumor cell-types" to be equivalent to the treatment of cancer.

5.1.6 Therefore, claim 1 of the main request is a product *"per se"* claim which is not restricted by the stated use, except as regards the suitability of the composition for the intended technical effect.

5.1.7 As regards the appellant's argument based on technical board of appeal decision T 290/86, it cannot succeed for the following reasons.

Enlarged Board of Appeal decision G 1/83 (G 5/83, G 6/83), OJ EPO 1985, 60 introduced the "Swiss-type" claim form in consideration of the fact that the provisions of EPC 1973, and in particular of its Article 54(5), allowed purpose-related product claims only for the first (generic) medical use of a known substance or composition. There was, however, an absence of provisions in EPC 1973 allowing purpose-limited product claims **for further specific medical indications** (see G 5/83, OJ EPO 1985, 64, point 15 of the Reasons and G 2/08, OJ EPO 10/2010, 456, points 5.8 and 5.9 of the Reasons).

By virtue of the legal fiction in accordance with the praetorian rule introduced with Enlarged Board of Appeal decision G 1/83 (G 5/83, G 6/83), the format of a "Swiss-type" claim, by definition, allowed claims directed to subject-matter referring to particular situations in which the "invention" for which protection was sought relied upon a new use of a substance or composition in a method of treatment referred to in Article 52(4) EPC 1973 (Article 53(c) EPC 2000).

Decision T 290/86 deals with claims in Swiss-type form. Apart from the fact that this claim format belongs to a different category than a purpose-limited product claim, the claim's format requires explicitly the feature "for the manufacture of a medicament" in order that the legal fiction conferring novelty on the subject-matter may be applied.

As the subject-matter of claim 1 of the main request is not in a "Swiss-type" format but in that of a purpose-related product claim, the findings in decision T 290/86 do not directly apply to the present case.

5.2 Novelty, Article 54(2) EPC

Document D2 discloses a liquid vitamin C concentrate composition comprising mineral ascorbate and at least 4-hydroxy-5-methyl-3(2H)-furanone and/or 3-hydroxy-kojic acid, each present in amounts of 0.001 wt.% to upwards of about 0.1 wt.% or more (D2 column 2, lines 41 and 58-60, column 3, lines 8-39, column 4, lines 14-19, column 11 second and third paragraphs). The upper value of 0.1 wt.% described for the secondary compound in the compositions of document D2 thus falls within the range of 0.01 to 1.0% by weight defined in claim 1 of the main request.

Hence, the compositions disclosed in document D2 comply with the definitions given in claim 1 of the main request for the features ii) to iv).

As regards feature i) in claim 1 of the main request, the compositions disclosed in document D2 are suitable for the intended purpose, as acknowledged on page 3 (end of first paragraph) of the present application as filed, where document D2 is referred to as an example

for the preparation of stable liquid compositions according to the "invention".

Consequently, the subject-matter of claim 1 of the main request lacks novelty vis-à-vis the disclosure of document D2 (Articles 52(1) and 54(2) EPC).

6. First auxiliary request

6.1 The subject-matter of claim 1 of the first auxiliary request differs from the subject-matter of claim 1 of the main request solely in that the amount of the secondary compound claimed is **up to 1.0% by weight of the total composition.**
Consequently, the upper value of 0.1 wt.% described for the secondary compound in document D2 also falls within the claimed range.

6.2 Hence, the subject-matter of claim 1 of the first auxiliary request lacks novelty (Articles 52(1) and 54(2) EPC) vis-à-vis the disclosure of document D2 for analogous reasons as outlined under point 5.2 above for the main request.

7. Third auxiliary request

7.1 The subject-matter of claim 1 of the third auxiliary request contains the feature of "the amount of secondary compound is from **0.2 to 1.0%** by weight of the total composition".
The application as originally filed describes an amount of 0.2 wt.% of the secondary compound solely in product B of example 1 for a specific composition comprising 96.5 wt.% sodium ascorbate, 0.2 wt.% 3-hydroxy-kojic acid and 3.3 wt.% other components.

7.2 The subject-matter of claim 1 of the third auxiliary request, however, is not restricted to product B of example 1 but relates to a more generic composition comprising "a vitamin C compound" in undefined amounts, in contrast to product B which necessarily contains 96.5 wt.% of sodium ascorbate.
Hence, the amount of 0.2 wt.% of 3-hydroxy-kojic acid described for the specific product B of example 1 cannot be singled out from this example, and combined with any thinkable "vitamin C compound" in any amount (up to 99.8 wt.%). Claim 1 of the third auxiliary request thus amounts to an unallowable generalisation of product B in example 1 of the application as filed.

7.3 Therefore, the third auxiliary request does not meet the requirements of Article 123(2) EPC.

8. Fourth auxiliary request

The subject-matter of claim 1 of the fourth auxiliary request relates to a composition containing "a vitamin C compound" and includes the feature "wherein the secondary compound is 3-hydroxy-kojic acid in an amount of **0.2%** by weight of the total composition". Therefore, the subject-matter of this claim is not restricted to product B of example 1.

Thus, the subject-matter of the fourth auxiliary does not meet the requirements of Article 123(2) EPC for analogous reasons to those given for the third auxiliary request under point 7 above.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated