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Datasheet for the decision of 14 June 2024

Case Number: T 1097/22 - 3.3.09

Application Number: 11833527.2

Publication Number: 2627197

IPC: G06F19/00, A23L33/00, A61K31/202

Language of the proceedings: EN

Title of invention:
OPTIMIZED NUTRITIONAL FORMULATIONS, METHODS FOR SELECTION OF TAILORED DIETS THEREFROM, AND METHODS OF USE THEREOF

Applicant:
Asha Nutrition Sciences, Inc.

Headword:
Optimised nutritional formulations/ASHA

Relevant legal provisions:
EPC Art. 123(2), 112(1)(a)

Keyword:
Amendments - allowable (no)
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:
G 0010/93, G 0002/10, T 0201/83, T 0068/99, T 3142/19, T 1149/20

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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 1097/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 14 June 2024

Appellant: (Applicant)	Asha Nutrition Sciences, Inc. P.O. Box 1000 Palo Alto, California 94302 (US)
Representative:	Lewis Silkin LLP Arbor 255 Blackfriars Road London SE1 9AX (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 29 November 2021 refusing European patent application No. 11833527.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	R. Romandini

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the applicant (appellant) against the examining division's decision to refuse the European patent application.

II. The examining division decided, among other things, that the main request did not comply with the requirement of Article 123(2) EPC. Auxiliary request 1 did not comply with other requirements of the EPC.

III. With the statement setting out the grounds of appeal, the appellant filed a main request and first auxiliary request.

IV. The appellant was summoned to oral proceedings. In a communication under Article 15(1) RPBA the board set out its preliminary opinion that, among other things, the amendments to claim 1 of both requests did not comply with the requirement of Article 123(2) EPC.

V. By letter dated 11 June 2024, the appellant provided further substantive submissions on the pending requests and informed the board that it would not be attending the oral proceedings. In the following these submissions will also be referred to as the "last submissions".

VI. Oral proceedings were held and at the end the decision was announced.

VII. The appellant's arguments relevant to the decision can be summarised as follows.

- The amendments to claim 1 of the main request and the first auxiliary request were based on the application as filed. The skilled person would have understood from the entirety of the application documents as filed that there was a pointer towards the combination of omega-6 fatty acids and antioxidants comprising polyphenols as well as the respective amounts.
- Substantially similar patent claims to those under examination on appeal had been allowed in parallel patents in 18 countries. If examiners in so many countries had been able to derive the claimed subject-matter from the original disclosure, it seemed reasonable that the same would be the case under the EPC.
- If the board were to find otherwise, a referral to the Enlarged Board of Appeal was requested.

VIII. Final requests

The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, the first auxiliary request, both requests filed with the statement setting out the grounds of appeal.

Reasons for the Decision

1. *Amendments - main request*

1.1 Claim 1 of the main request reads as follows:

"1. *A product comprising one or more nutritional formulations for an individual, wherein the one or more formulations are so packaged and labelled indicating suitability for consumption that collectively provides a dosage of:*
i) 1 to 40g of omega-6 fatty acids; and
ii) 25mg-10g of antioxidants comprising greater than 5 mg of one or more polyphenols."

1.2 Claim 1 of the main request is identical to claim 1 of the main request on which the decision under appeal was based.

1.3 According to G 10/93, in an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the authority to examine requirements which the examining division either did not consider during the examination proceedings or deemed to have been met.

1.4 Whether an amendment complies with the requirement of Article 123(2) EPC is assessed by applying the "gold standard" (G 2/10). Under the EPC, an amendment to the application documents can only be made within the limits of what a skilled person would have derived directly and unambiguously, using common general knowledge, from the whole (i.e. the entirety) of the application documents. In particular, what has to be

examined is not only whether there is a basis for the individual features added by the amendment but also whether the skilled person would have derived the combination of those features and the other features of the claim directly and unambiguously from the application as filed.

1.5 The examining division assessed an amendment involving the same combination of features as claim 1 of the main request (omega-6 fatty acids, antioxidants and one or more polyphenols and the respective amounts) in auxiliary request 1 before it. It found that the basis for the amendment was in paragraphs [0150], [0151] and [0164] of the application as filed.

1.6 These passages read as follows.

"*[0150] In some embodiments, polyphenols, folate, phytosterols, alpha carotene, beta carotene, beta cryptoxanthin, betaine, choline, lycopene, and lutein/ zeaxanthin are included in the formulations. For example, one or more polyphenols greater (or less) than 5, 10, 15, 20, 45, 70, 95, 115, 140, 165, 200, or 300 mg/day; and/or folate greater (or less) than ...*"

"*[0151] In some embodiments, antioxidants, and vitamins and minerals, e.g. Se are included in the formulations. For example, antioxidants greater (or less) than 25, 50, 100, 200, 400, 500, 600, or 1000 mg per day, or 1, 2, 4, 6, 8, or 10g per day; and/or Se greater (or less) than ...*"

"*[0164] In some embodiments the average daily amount of omega-6 fatty acid according to the nutritional program ranges between 1-40 g. In embodiments, the daily amount*

of omega-6 fatty acid is more (or less) than 1, 2, 5, 10, 15, 20, 25, 30, 35, or 40g."

1.7 However, neither claim 1 of the application as filed nor the other sections of the application as filed disclose – exclusively – the combination of features called for in claim 1. In the passages of the description on pages 47 to 48 (from paragraph [0147] to paragraph [0165]), the application as filed discloses further nutritional components and daily dosages that have not been included in claim 1. They relate for example to fibres and ratios of omega-3, omega-6, omega-9, saturated, monounsaturated and polyunsaturated fatty acids.

1.8 In view of this, no pointer towards the specific combination of features called for in claim 1, which involves several selections, can be found in the application as filed.

1.9 While the skilled person could have gathered from the application as filed that omega-6 fatty acids were a relevant aspect of the application as filed, the same cannot be said for the antioxidants and the polyphenols. These two groups of components are taken from a long list of components that may be used in a number of embodiments disclosed on pages 47 and 48 of the application as filed.

1.10 In more detail, paragraph [0150] mentions polyphenols in a list that also mentions folate, phytosterols, alpha carotene, beta carotene, beta cryptoxanthin, betaine, choline, lycopene and lutein/zeaxanthin. There is no pointer towards choosing the polyphenols. Similarly, paragraph [0151] mentions antioxidants,

vitamins and minerals, in particular selenium. There is no pointer towards the antioxidants.

1.11 Furthermore, the ranges of antioxidant and polyphenol dosages called for in claim 1 under consideration are not directly and unambiguously derivable from the application as filed.

1.12 For example, paragraph [0150] discloses that polyphenols are administered at "greater (or less) than 5, 10, 15, ... mg/day". It is plain to see that a dosage of less than 5 mg/day is explicitly disclosed and envisaged. In other words, this specific dosage is disclosed as both a maximum and a minimum dosage.

1.13 Analogous considerations apply to the dosage of antioxidants (greater or less than 25 mg per day).

1.14 In its last submissions, the appellant argued that paragraph [0037] of the application as filed confirmed that the envisaged collective dosage of polyphenols was greater than 5 mg. Moreover, the term in parentheses, "(or less)", in paragraph [0150] of the application as filed referred to non-essential information, the essential information actually being "greater ... than 5 ... mg/day".

1.15 However, the passage on paragraph [0037] discloses that "in a particular example, the formulations delivering the micronutrients may deliver polyphenols at about 5, 10, 15, 20, 45, 70, 95, 115, 140, or 165 mg/day". The disclosure of about 5 mg/day is technically entirely compatible with the disclosure of less than 5 mg/day; the value range of "about 5" includes values both above and below 5. The broad disclosure of the application as filed simply encompasses these two ranges.

1.16 In its last submissions, the appellant referred to passages of the application as filed that allegedly supported the amendments made, and presented the following arguments.

- The focus of examples 7 to 14 of the application as filed was omega-6 fatty acids; example 8.2 only recited the omega-6 dose in the context of antioxidants and phytochemicals.

- Antioxidants appeared umpteen times in the application as filed. This constituted a pointer towards the antioxidants.

- It was known in the art and disclosed in the application as filed that there was an overlap between micronutrients, phytochemicals and antioxidants (e.g. paragraphs [0025] and [0059]). Moreover, polyphenols were a subgroup of antioxidants.

1.17 However, these arguments are not convincing either.

1.18 The examples cited by the appellant do not support the combination of features and ranges in claim 1. To begin with, these examples mention not only omega-6 fatty acids but also omega-3 fatty acids, for which a daily dosage is disclosed in the application as filed (paragraph [0165]). However, if the examples were indeed to support the amendment, then it has to be noted that claim 1 does not require a daily dosage of omega-3 fatty acids. Therefore, the examples and claim 1 are in contradiction.

1.19 This confirms the board's assessment that there is no pointer leading the skilled person to the specific combination of features required by claim 1. The features had been combined in the course of the examination proceedings. The combination was not directly and unambiguously disclosed in or derivable from the application as filed.

1.20 Next, while it is true that the application as filed mentions antioxidants many times, it also mentions omega-3 fatty acids, vitamins and minerals. Therefore, even though antioxidants are mentioned many times in the application as filed, a direct and unambiguous disclosure of the combination of features required by claim 1 is not clearly derivable from the application as filed.

1.21 The appellant argued that the application as filed referred to phytochemicals, antioxidants, vitamins and minerals as overlapping concepts, and that phytochemicals/antioxidants "expressly call out polyphenols without exception" (emphasis in the original). However, it is precisely these overlapping concepts that fail to provide a clear, direct and unambiguous disclosure of the combination of features of claim 1. The disclosure of the application as filed is broad and ambiguous on the very aspects of its teaching that are relevant to the invention. This is reflected in the features added to the claim: phytochemicals may or may not be antioxidants, and antioxidants within the meaning of the application as filed (paragraph [0075]) are not only polyphenols - glutathione and enzymes are also encompassed.

1.22 The appellant cited some board of appeal decisions which had found that an indication in the description

that some combination was desirable constituted a clear pointer towards that combination. Examples of these decisions included T 68/99, T 3142/19 and T 1149/20.

1.23 However, what constitutes a pointer within the disclosure of each individual patent application has to be decided on a case by case basis. What is relevant for such an assessment is the direct and unambiguous disclosure of the entire application as filed under consideration (see point 1.4 above). In the current case, for the reasons given above, no such pointer towards the combination of features of claim 1 has been identified.

1.24 Regarding the value ranges included in claim 1, the appellant referred to T 201/83, in view of which it was permissible under the EPC to insert limiting numerical values from a specific disclosure into the general teaching of healthful dosages of antioxidants comprising polyphenols.

1.25 However, the application as filed in the case on which the cited decision is based related to lead alloys which contained calcium and magnesium in specified narrow amounts. The working and comparative examples of the application illustrated the effectiveness of the magnesium content in preventing calcium loss. The question was simply whether the amendment restricting the amounts of these two metals was allowable. While in that case the components were always only magnesium and calcium in combination with a value range, the situation is different in the case in hand. As explained above, the first question is whether the restriction to the specific combination of features, including antioxidants and polyphenols, is allowable at all.

1.26 Lastly, the appellant argued that similar claims had been allowed in parallel patents in 18 countries. Since examiners in this many countries were able to derive the claimed subject-matter from the original disclosure, it seemed reasonable that the same would be the case under the EPC.

1.27 However, this argument does not affect the previous assessment. Patent examination outcomes in different jurisdictions do not need to be the same. Criteria for allowing amendments to the application as filed can vary. Even if the rules are similar and the disclosures and claims identical, different authorities may reach different conclusions. This is also true under the EPC, when a board of appeal reviews a refusal decision of the examining division as well as when an opposition division examines an opposition against a granted patent. Moreover, the EPO is not bound by other jurisdictions' conclusions.

1.28 To conclude, for the reasons set out above, the amendments made to claim 1 of the main request contravene the requirement of Article 123(2) EPC.

2. *Amendments - first auxiliary request*

2.1 Claim 1 of the first auxiliary request differs from claim 1 of the main request only in that the term "dosage" has been replaced (and restricted) by the term "daily dosage". The wording of claim 1 of the first auxiliary request is identical to the wording of claim 1 of auxiliary request 1 of the decision under appeal.

2.2 For the reasons already explained, the restriction to the feature "daily dosage" does not resolve the objections identified above for claim 1 of the main request.

2.3 In view of this, the combination of features in claim 1 of the first auxiliary request is not directly and unambiguously derivable from the application as filed (Article 123(2) EPC). On this basis alone, the first auxiliary request is not allowable.

3. *Referral*

3.1 The appellant made conditional requests for a referral to the Enlarged Board of Appeal, in particular if the board were to find otherwise on the argument that similar patent claims had been allowed in parallel patents in 18 countries and the same should occur under the EPC. However, the appellant did not formulate any specific question to be referred, nor is it clear to the board what this legal question should be.

3.2 Under Article 112(1)(a) EPC, a board may refer any question to the Enlarged Board of Appeal if it considers that a decision is required to ensure uniform application of the law or if a point of law of fundamental importance arises.

3.3 In the case in hand the board sees no reason to *ex officio* formulate and refer any question to the Enlarged Board of Appeal. The board was able to deal with all the legal issues at play. Moreover, no point of law of fundamental importance that would require an answer from the Enlarged Board of Appeal has been identified.

3.4 Therefore, the appellant's request for (unspecified) questions to be referred to the Enlarged Board of Appeal is rejected (Article 112(1)(a), last sentence, EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated