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Datasheet for the decision of 14 June 2024

Case Number: T 1054/22 - 3.3.09

Application Number: 17182663.9

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Language of the proceedings: EN

Title of invention:
LIPID-CONTAINING COMPOSITIONS AND METHODS OF USE THEREOF

Applicant:
Asha Nutrition Sciences, Inc.

Headword:
Liquid-containing composition/ASHA

Relevant legal provisions:
EPC Art. 76(1), 112(1)

Keyword:
Divisional application - added subject-matter (yes)
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:
G 0003/89, G 0011/91, G 0001/93, G 0002/10, G 0001/16

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Case Number: T 1054/22 - 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. 17182663.9 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 neither the main request nor auxiliary request 1 before it complied with the requirement of Article 76(1) EPC.

III. With its statement setting out the grounds of appeal, the appellant filed a main request and an auxiliary request 1. The two claim requests on appeal each include an additional claim that had not been in the claim requests before the examining division. Apart from this, the claims on appeal and those examined in the impugned decision are identical.

IV. The appellant was summoned to oral proceedings. In a communication under Article 15(1) RPBA, the board set out its preliminary opinion that the amendments did not comply with the requirement of Article 76(1) EPC, among other things.

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 argument relevant to the decision can be summarised as follows:

- Applying the criteria of decision G 1/93 of the Enlarged Board of Appeal, the amendments made did not result in an unwarranted advantage. Therefore, they were allowable.
- The amendments made to claim 1 of the main request were based on the entirety of the earlier application as filed. This applied in particular to the amendments concerning the omega-6 to omega-3 ratio of 4:1 or greater and the concentration of omega-6 fatty acids (4-75% by weight of total lipids) and omega-3 fatty acids (0.1-30% by weight of total lipids).
- These considerations also applied to auxiliary request 1.
- 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, on the basis of auxiliary request 1, both requests being filed with the statement setting out the grounds of appeal.

Reasons for the Decision

1. *Admittance of requests*

As will be seen in the following, the main request and auxiliary request 1 are not allowable under Article 76(1) EPC. Therefore, the question as to whether these requests are admissible on appeal need not be examined.

2. *Main request - amendments*

2.1 The examining division concluded that claim 1 of the main request before it did not comply with the requirements of Articles 123(2) or 76(1) EPC, among other things. That claim has the same wording as claim 1 of the main request on appeal.

2.2 This application is a European divisional application. Its description and claims as filed are identical to those of the earlier application as filed, which had been filed as an international application and published as WO 2009/131939 A2.

2.3 Whether an amendment complies with the requirements of Articles 123(2) and 76(1) EPC is assessed using the "gold standard". This term was coined in decision G 2/10 of the Enlarged Board of Appeal (Reasons, 4.3), in which the jurisprudence developed by the Enlarged Board of Appeal in opinion G 3/89 and decision G 11/91 was confirmed. 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.

2.4 In its last submissions, the appellant cited a passage from decision G 1/93 of the Enlarged Board of Appeal (Reasons, 16). The appellant's argument here is understood to be that if an added feature excluded protection for part of the subject-matter of the claimed invention as covered by the application as filed, the adding of such a feature could not be considered to give any unwarranted advantage to the applicant. In short, a restriction of the claim based on disclosure from the application as filed did not contravene Article 123(2) EPC.

2.5 Primarily, decision G 1/93 concerns a case in which a granted claim cannot be maintained unamended in opposition proceedings because the claim is found to contravene Article 123(2) EPC. G 1/93 therefore concerns a case in which an examining division allowed an amendment it should not have allowed. As explained in detail in G 2/10 (Reasons 4.3, last paragraph), decision G 1/93 is not intended to modify the general definition of the requirements of Article 123(2) EPC (and Article 76(1) EPC) established in opinion G 3/89 and decision G 11/91, i.e. the "gold standard".

2.6 According to G 1/93, the purpose of Article 123(2) EPC (and Article 76(1) EPC) is to prevent an applicant from gaining an unwarranted advantage by obtaining patent protection for something it had not properly disclosed on the date of filing of the application. An added feature limiting the scope of the claim may still contravene Article 123(2) EPC. An example of this, explicitly mentioned in G 1/93, is a limiting feature that creates an inventive selection not disclosed in

the application as filed or otherwise derivable therefrom.

2.7 As an intermediate conclusion, for assessing whether the amendments in claim 1 contravene Article 123(2) EPC or Article 76(1) EPC, the "gold standard" has to be applied. This is in agreement with G 1/93.

2.8 In the following, the board will only examine whether or not the amendments are based on the earlier application as filed, i.e. whether or not the subject-matter of claim 1 complies with the requirement of Article 76(1) EPC.

2.9 Claim 1 of the earlier application as filed reads as follows:

"*A lipid-containing composition comprising daily optimal amounts of fatty acids and phytochemicals for a mammalian subject based on one or more factors selected from the following group: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, medical conditions of the subject, and climate of the subject's living area*."

2.10 Claim 1 of the main request reads as follows:

"*A lipid-containing formulation for a subject, comprising a mixture of lipids from different sources and a dosage of omega-6 fatty acids, wherein the formulation further comprises:*

a) a dosage of omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:

(i) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or

(ii) dosage of omega-6 fatty acids is not more than 40 grams; or

b) polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from: phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols."

2.11 It is plain to see that the amendments made to claim 1 of the earlier application as filed involve several modifications. More specifically, value ranges have been added to claim 1 of the main request, in features a), (i) and (ii). The question to be answered is whether or not the skilled person would have derived these amendments directly and unambiguously, using common general knowledge, from the entirety of the earlier application documents as filed. What has to be examined is not only whether there is a basis for each of the features added by the amendments but also

whether the skilled person would have derived the combination of features a), (i) and (ii), and that combination of features alone, from the earlier application as filed.

2.12 Although the examining division identified several amendments contravening Articles 123(2) EPC and 76(1) EPC in claim 1 and the dependent claims, the board will focus on only some of the features of claim 1.

2.13 Feature (i) of claim 1

2.13.1 This feature concerns the amendment that the dosage of omega-6 fatty acids is 4-75% by weight of total lipids and that of omega-3 fatty acids is 0.1-30% by weight of total lipids.

2.13.2 No basis can be found in the earlier application as filed for the combination of the concentration of omega-6 fatty acids of 4-75% by weight of total lipids and omega-3 fatty acids of 0.1-30% by weight of total lipids.

2.13.3 The appellant referred to claim 3 of the earlier application as filed. Yet this claim discloses neither a specific concentration nor a specific ratio for the omega-6 fatty acids and the omega-3 fatty acids.

2.13.4 Throughout the examination and appeal proceedings, the only passage of the earlier application as filed that has been mentioned as being a possible basis for the value ranges 4-75% and 0.1-30% is table 4. However, these value ranges are disclosed in conjunction with specific value ranges of omega-9 fatty acids (10-90%) and Vitamin E (0.001-0.5%). This disclosure is not included in claim 1 of the main request.

2.13.5 In its last submissions, the appellant argued that it was physically impossible for the ratios/contents recited in table 4 to be present in a single composition, because they would add up to 195%.

2.13.6 This is not convincing. It cannot be seen why a composition comprising Vitamin E, omega-9 fatty acids at 90% by weight of total lipids, omega-6 fatty acids at slightly above 4% by weight of total lipids and omega-3 fatty acids at slightly above 0.1% by weight of total lipids would be physically impossible to formulate. The original disclosure of the earlier application as filed is simply very broad. It encompasses a wide range of compositions that can be drawn up using, and staying within, the ranges disclosed in table 4. One embodiment is the composition exemplified above.

2.13.7 The appellant also referred to G 1/93. As explained above, this decision does not set aside the "gold standard"; the contrary is true. Furthermore, the skilled person would not have considered omega-9 fatty acids to be irrelevant to the formulation disclosed in table 4 of the earlier application as filed. These fatty acids manifestly provide a technical contribution to the composition of the diet. In fact, table 4 calls for at least 10% by weight of total lipids of omega-9 fatty acids. This is also clearly apparent from the entirety of the earlier application as filed and especially from its examples, e.g. tables 6, 14 and 16, to name a few.

2.13.8 In this context, the appellant referred to examples 12 to 27, which allegedly only referred to omega-6 and omega-3 fatty acids. However, these examples do not

directly and unambiguously disclose the range specified in feature (i). Furthermore, these examples disclose the administration of further components. For instance, example 12 discloses a composition of vegetable oils, nuts and seeds. The skilled person would know that these components typically contain vitamin E and omega-9 fatty acids, i.e. the components listed in table 4.

2.13.9 As an intermediate conclusion, feature (i) alone is not directly and unambiguously derivable from the earlier application as filed.

2.14 Feature a) of claim 1

2.14.1 This feature concerns the amendment that the ratio of omega-6 to omega-3 is 4:1 or greater.

2.14.2 There is no basis in the earlier application as filed for an open-ended ratio of omega-6 to omega-3 fatty acids of 4:1 or greater. The appellant referred to claim 3 of the earlier application as filed but this claim discloses no values at all. It cannot be seen how claim 3 alone gives rise to the amendment made in claim 1 of the main request.

2.14.3 Table 3 of the earlier application as filed discloses a range of ratios of 1:1 to 1:50. This is not the range specified in claim 1.

2.14.4 Although table 9 of the earlier application as filed discloses a range of ratios starting at 4:1, it also specifies a highest ratio of 45:1. This table discloses lipid dosages for specified groups of consumers based on age and sex. The upper value of the ratio range is

not included in claim 1, however. This amendment contravenes Article 76(1) EPC on this basis alone.

2.15 Feature (ii) of claim 1

2.15.1 This feature concerns the amendment that the dosage of omega-6 fatty acids is not more than 40 grams.

2.15.2 In the earlier application as filed, the dosage of omega-6 fatty acids per day (40 grams) is always disclosed in combination with a minimum amount. There is no teaching that the lower amount can be neglected or dispensed with. This amendment in claim 1 therefore contravenes Article 76(1) EPC.

2.15.3 It should be noted here that in the earlier application as filed (e.g. in table 9) the amounts for the dosage of omega-6 fatty acids are directly and unambiguously disclosed in combination with a target group of consumer, defined by gender and age. This dosage is also disclosed in combination with a dosage of omega-3 fatty acids. None of this information is included in claim 1.

2.15.4 However, the skilled person would not understand from the earlier application as filed that the information on the target user or further compositional requirements is irrelevant. Claim 1 of the earlier application as filed in fact suggests the contrary (see point 2.9 above).

2.15.5 The appellant referred to several passages of the earlier application as filed in which no minimum value was disclosed. However, since these passages do not disclose a maximum dosage either, they cannot be used to support the amendment in feature (ii) of claim 1.

2.16 In view of what is stated above, the combination of features a), (i) and (ii) of claim 1 is also not directly and unambiguously derivable from the earlier application as filed.

2.17 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.

2.18 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 applications as filed can vary. Even with similar rules and based on identical disclosures and claims, 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.

2.19 To conclude, claim 1 of the main request does not comply with the requirement of Article 76(1) EPC.

3. *Auxiliary request 1 - amendments*

3.1 The examining division concluded that the subject-matter of claim 1 of auxiliary request 1 also involved added subject-matter.

3.2 Claim 1 of auxiliary request 1 reads as follows:

"*A lipid-containing formulation for a subject, comprising a mixture of lipids from different sources and a dosage of omega-6 fatty acids, wherein the formulation further comprises:*

a dosage of omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 to 45:1, wherein omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids".

3.3 This claim encompasses amendments involving the added features discussed in point 2.13 above. As explained with respect to the main request, this amendment alone involves added subject-matter. The same applies in the context of auxiliary request 1. The appellant has not provided any further lines of argument with respect to this claim request.

3.4 On this basis alone, claim 1 of auxiliary request 1 does not comply with the requirement of Article 76(1) EPC.

4. *Referral*

4.1 The appellant made several conditional requests for a referral to the Enlarged Board of Appeal, in case the board were to hold otherwise on several issues. The appellant did not formulate any specific legal questions to be referred.

4.2 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.

4.3 In the case in hand, the board sees no reason to *ex-officio* formulate and refer any legal questions to the Enlarged Board of Appeal. The board was able to deal with all the legal issues at play. The uniform application of Articles 123(2) and 76(1) EPC is ensured by applying the "gold standard" that has been repeatedly confirmed by Enlarged Board of Appeal decisions, including G 1/16 (Reasons, 17 and following). Moreover, no point of law of fundamental importance that would require an answer from the Enlarged Board of Appeal has been identified.

4.4 Therefore, the appellant's requests for the referral of (unspecified) questions to the Enlarged Board of Appeal are 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