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**Datasheet for the decision
of 9 April 2024**

Case Number: T 2074/22 - 3.3.07

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Language of the proceedings: EN

Title of invention:
DEBILITY PREVENTATIVE

Patent Proprietor:
AJINOMOTO CO., INC.

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Debility Preventative / AJINOMOTO

Relevant legal provisions:

EPC Art. 53(c), 123(2)

RPBA 2020 Art. 13(2), 13(1)

Keyword:

Exceptions to patentability - method for treatment by therapy

Amendments - undisclosed disclaimer - extension beyond the
content of the application as filed (yes)

Late-filed request - admitted (no)

Decisions cited:

G 0001/03, T 2275/18, T 1635/09, T 0767/12



Beschwerdekammern
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 2074/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 9 April 2024

Appellant: AJINOMOTO CO., INC.
(Patent Proprietor) 15-1, Kyobashi 1-chome
Chuo-ku
Tokyo 104-8315 (JP)

Representative: Mewburn Ellis LLP
Aurora Building
Counterslip
Bristol BS1 6BX (GB)

Appellant: Fresenius Kabi Deutschland GmbH
(Opponent) Else-Kröner-Stasse 1
61352 Bad-Homburg v.d.H. (DE)

Representative: Fresenius Kabi Deutschland GmbH
Patent Department
Pharmaceuticals Division
Borkenberg 14
61440 Oberursel (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 July 2022 concerning maintenance of the
European Patent No. 3115047 in amended form.**

Composition of the Board:

Chairman A. Uselli
Members: E. Duval
L. Basterreix

Summary of Facts and Submissions

- I. An opposition was filed against the patent in suit on the grounds that its subject-matter lacked novelty and inventive step, it was excluded from patentability under Article 53(c) EPC, it was not sufficiently disclosed and it extended beyond the content of the application as filed.
- II. The appeals were filed by the opponent (appellant - opponent) and the patent proprietor (appellant - proprietor) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 9, the patent met the requirements of the EPC.

The decision was based on a main request and auxiliary requests 1-7 filed on 30 June 2021, auxiliary request 8 filed on 4 February 2022 and auxiliary request 9 filed during oral proceedings on 19 April 2022.

The main request contained 5 independent claims, among which claims 1, 11 and 17:

claim 1: "An agent for use in the prophylaxis or improvement of frailty, comprising isoleucine and threonine as active ingredients, wherein the content of amino acids other than tryptophan, threonine, methionine and isoleucine is not more than 40 wt% of the amino acid contained, and wherein the frailty is at least one kind of symptom selected from the group consisting of loss of muscle mass, decline in grip strength, feeling of fatigue, depression state, delirium, dementia, sleep disorder, anxiety disorder and social withdrawal, in an elderly person."

claim 11: "Non-therapeutic use of an agent for the prophylaxis or improvement of frailty, comprising isoleucine and threonine as active ingredients, wherein the content of amino acids other than tryptophan, threonine, methionine and isoleucine is not more than 60 wt% of the amino acid contained, and wherein the frailty is at least one kind of symptom selected from the group consisting of decrease in walking speed, decrease in the amount of physical activity and loss of motivation, in an elderly person."

claim 17: "Non-therapeutic use of a food or drink for the prophylaxis or improvement of frailty, which is in a unit package form per serving comprising not less than 0.04 g of isoleucine and threonine in total as an active ingredient at a weight ratio of isoleucine and threonine of 1:0.2 - 10, wherein the content of amino acids other than tryptophan, threonine, methionine and isoleucine is not more than 40 wt% of the amino acid contained, and wherein the frailty is at least one kind of symptom selected from the group consisting of decrease in walking speed decrease in the amount of physical activity and loss of motivation, in elderly person."

In auxiliary request 9, claim 1 and claim 9 corresponded respectively to claim 1 and claim 11 of the main request, wherein the agent was amended to comprise "isoleucine, threonine, tryptophan and methionine as active ingredients, wherein the agent is free of an amino acid other than tryptophan, threonine, methionine and isoleucine".

III. The opposition division decided in particular that:

(a) Claims 1 and 11 of the main request did not meet the requirements of Article 123(2) EPC with respect to the feature pertaining to the content of amino acids other than tryptophan, threonine, methionine and isoleucine. The same conclusion also applied to auxiliary requests 1-7.

(b) Auxiliary request 9 complied with Articles 123(2) and 83 EPC. The indications of claims 9-14 were considered to be non-therapeutic, such that these claims did not contravene Article 53(c) EPC.

IV. During the appeal proceedings, the appellant - proprietor successively filed:

- with the grounds of appeal dated 15 November 2022, the same main request as underlying the appealed decision, as well as auxiliary requests 1-28,
- by letter dated 22 August 2023, auxiliary requests 17A, 18A, 19A, 20A and 25A,
- by letter dated 30 March 2023, auxiliary request 29,
- by letter dated 19 February 2024, auxiliary requests 30-31, and
- during the oral proceedings before the Board, auxiliary requests 32-33.

Each of the auxiliary requests 1-29, 17A-20A and 25A comprised a claim corresponding to claim 11 or 17 of the main request, directed at the non-therapeutic use of an agent, or food or drink, for the prophylaxis or improvement of frailty, and amended in that:

- the content of amino acids other than tryptophan, threonine, methionine and isoleucine was not more than 40 wt%, and/or
- the agent, or food or drink, further comprised tryptophan and methionine, and wherein further in some requests:

- the agent, or food or drink, was free of an amino acid other than tryptophan, threonine, methionine and isoleucine, and/or
- the weight (%) of tryptophan, threonine, methionine and isoleucine in the free amino acid in the agent was 5% - 33%, 8%- 60%, 10% - 40% and 8% - 60% respectively, and/or
- either "loss of motivation" or " decrease in the amount of physical activity" was deleted from the symptoms.

Auxiliary requests 30-33 did not contain any claims directed to uses:

Claim 1 of auxiliary request 30 related to: "An agent for use in the prophylaxis or improvement of frailty, comprising isoleucine, threonine, tryptophan and methionine as active ingredients, wherein the agent is free of an amino acid other than tryptophan, threonine, methionine and isoleucine, and wherein the frailty is at least one kind of symptom selected from the group consisting of loss of muscle mass, decline in grip strength and feeling of fatigue, in an elderly person."

In claim 1 of auxiliary request 31, the "feeling of fatigue" was deleted from the symptoms.

Auxiliary requests 32 and 33 corresponded to auxiliary requests 30 and 31, wherein in claim 1 the expression "free" was replaced with "substantially free".

V. The appellant - proprietor's arguments may be summarised as follows:

- (a) Regarding the main request, due to the presence of the term "non-therapeutic" in claims 11-18, any

possible medical uses were excluded from the claims, such that these claims 11-18 could not be considered to be in violation of Article 53(c) EPC. Furthermore, T 2275/18 clearly set out that all activities which may result in retaining health were not to be considered as therapeutic methods, in particular if they related to natural and common daily activities. The insertion of the term "non-therapeutic" constituted an allowable undisclosed disclaimer in the sense of G 1/03, consistent with Article 123(2) EPC.

- (b) As to auxiliary requests 30 and 31, the feature that the agent be free of an amino acid other than isoleucine, threonine, tryptophan and methionine derived from paragraph [0053] of the application as filed. The deletion of "substantially" was standard practice and did not infringe Article 123(2) EPC, because the skilled person would understand "substantially free" as "free", as confirmed by the examples.
- (c) Auxiliary requests 32 and 33, wherein the term "substantially" was re-introduced in claim 1, were to be admitted into the proceedings, because they were filed in reaction to the Board's unexpected finding that the deletion of this term infringed Article 123(2) EPC. The term was clear based on its definition in the patent.

VI. The appellant - opponent's arguments may be summarised as follows:

- (a) Claims 1 and 11 of the main request required the identical use (the prophylaxis or improvement of frailty), the identical compositional features (the

agent defined therein) and the identical target group (an elderly person). The patent did not discriminate between any therapeutic and non-therapeutic frailty symptoms, or use in the prophylaxis or improvement of frailty. To the extent that claim 1 of the main request was interpreted as a medical use claim in the sense of Article 54(5) EPC, the subject-matter of claims 11-18 was excluded from patentability under Article 53(c) EPC. Furthermore, the application as filed did not disclose any "non-therapeutic" use, such that the subject-matter of claims 11-18 violated the requirements of Article 123(2) EPC.

- (b) Claim 1 of auxiliary requests 30 and 31 required that the agent is free of an amino acid other than isoleucine, threonine, tryptophan and methionine. However, the application as filed did not disclose an agent that is completely free of other amino acids, but only that the agent is "substantially free" of these other amino acids. According to paragraph [0053], "being substantially free means that the object and effect of amino acids (1) - (4) are not influenced". Therefore, auxiliary requests 30 and 31 violated Article 123(2) EPC.

- (c) The filing of auxiliary requests 32 and 33 was not justified by exceptional circumstances. The objection against the feature "free" had been addressed in the appealed decision and raised in the appeal proceedings. It was in the nature of the appeal proceedings that the opposition division's finding may be set aside. In addition, the re-establishment of the term "substantially" introduced new issues of clarity. Hence, these

late-filed requests were not to be admitted into the appeal proceedings.

- VII. The appellant - proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of:
- the main request filed with the statement setting out the grounds of appeal on 15 November 2022,
 - or, alternatively, one of
 - auxiliary requests 1-28 filed on 15 November 2022,
 - auxiliary request 29 filed on 30 March 2023, and
 - auxiliary requests 17A, 18A, 19A, 20A and 25A filed on 22 August 2023,
- the order of the requests being as set out in Annex 1 of the letter dated 22 August 2023,
- auxiliary requests 30 and 31 filed on 19 February 2024, or
 - auxiliary requests 32 and 33 filed during the oral proceedings before the Board.
- VIII. The appellant - opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety. The appellant - opponent further requested that auxiliary requests 8, 11, 19, 17A, 18A, 19A, 20A, 25A and 30-33 not be admitted into the proceedings.

Reasons for the Decision

1. Main request, Articles 123(2) and 53(c) EPC
- 1.1 In the main request, claims 1-10 are drafted as purpose-limited products claims in the format of

Article 54(5) EPC, whereas claims 11-18 pertain to uses.

Claim 1 relates to:

- an agent (as defined therein)
- for use in the prophylaxis or improvement of frailty in an elderly person
- wherein the frailty is at least one kind of symptom selected from the group consisting of
 - loss of muscle mass,
 - decline in grip strength,
 - feeling of fatigue,
 - depression state,
 - delirium,
 - dementia,
 - sleep disorder,
 - anxiety disorder and
 - social withdrawal.

Claims 11 and 17 relate to

- the non-therapeutic use of an agent, or a food or drink,
- for the prophylaxis or improvement of frailty in an elderly person,
- wherein the frailty is at least one kind of symptom selected from the group consisting of
 - decrease in walking speed,
 - decrease in the amount of physical activity and
 - loss of motivation.

1.2 In claims 11 and 17, the expression "non-therapeutic" was introduced by way of an amendment as an undisclosed disclaimer in the sense of G 1/03.

It is established case law that a disclaimer "non-therapeutic" allows for the exclusion of therapeutic

uses from a claim encompassing both therapeutic and non-therapeutic uses in such a way that they are substantively separable, so that the remaining subject-matter is no longer covered by the exception to patentability under Article 53(c) EPC. However, such a disclaimer cannot be employed to define as non-therapeutic a use which necessarily includes one or more therapeutic steps (see the Case Law of the Boards of Appeal, 10th edition, 2022, I.B.4.5.3).

- 1.3 According to the appellant - proprietor, the uses defined in claim 11, namely decrease in walking speed, decrease in the amount of physical activity and loss of motivation, cover non-therapeutic uses which can be distinguished, or separated, from therapeutic uses.

However, in the Board's view, claims 11 and 17 do not generally relate to decrease in walking speed, decrease in the amount of physical activity and loss of motivation. Instead, claim 11 and 17 explicitly relate to these conditions only in the context of the prophylaxis or improvement of frailty in an elderly person.

In this respect, it is also established case law that a prophylactic treatment, aimed at maintaining health by preventing ill effects that would otherwise arise, amounts to a method for treatment by therapy as referred to in Article 53(c) EPC. Therapy is not limited to treatments which restore health by curing diseases which have already arisen. Both prophylactic and curative methods of treating diseases are covered by the word therapy, since both are directed to the maintenance or restoration of health (see the Case Law of the Boards of Appeal, 10th edition, 2022, I.B.4.5.1.b).

In the present case, even if the symptoms of frailty in elderly people are not necessarily considered an illness as such (see paragraph [0036] of the patent), the prevention of these symptoms necessarily aims at least at maintaining health in the patient. The description makes clear that the prophylaxis of frailty is previous prevention of its symptoms from being developed, and the improvement of frailty includes bringing these symptoms to fall within a normal range, as well as preventing the progression or exacerbation of the disease (see paragraph [0039]). It is also explained that the prophylaxis of frailty leads to the prevention or delaying of a transfer to a condition in need of nursing care and increases health expectancy (see paragraph [0003]).

The Board additionally notes that the appellant - proprietor's argumentation on novelty and inventive step of claim 1 of the main request rather contradicts their position regarding the non-therapeutic nature of the use of claim 11. The appellant - proprietor submitted that claim 1 relates to the prophylaxis or improvement of frailty, and that the present invention is aimed at preventing and alleviating the ill effects that would otherwise arise in elderly populations, so as to maintain health, such that claim 1 should be considered to be a use limited product claim in accordance with Article 54(5) EPC (see the appellant - proprietor's reply dated 30 March 2023, §5 and §6.2.3; see also their grounds of appeal, §5 on page 5). Following this reasoning, in which the particular symptoms recited in claim 1 play no role, the same indication against frailty in claim 11 must also be regarded as therapeutic.

1.4 The appellant - proprietor, citing decision T 2275/18, criticised this approach as it would imply that even the most natural and common daily activities, such as taking a protein bar (which would contain amino acids compositions) before going to the gym, would always be considered as therapeutic methods.

The Board does not share this view. In case T 2275/18, the claim at hand related to a non-therapeutic method of applying to human skin a personal care composition. The respondent had argued that applying a composition comprising a UV-A sunscreen agent to human skin must always be regarded as a therapy, since the prophylactic effect against sunburn could not be separated from cosmetic uses. The competent Board did not accept this position, because this approach would imply that even the most natural and common daily activities, such as washing or putting on clothes, would always be considered as therapeutic methods (see point 5. of the reasons). Importantly, the Board further reasoned that it was possible to carry out the claimed method on human skin which is neither in a pathological state nor likely to develop one (e.g. by using the composition as a shower gel).

The present case has no relation with the situation underlying T 2275/18. The activity imagined by the appellant - proprietor would suppose, in the context of claim 11, that the patient taking a protein bar before going to the gym is an elderly presenting or developing symptoms of frailty, and that the protein bar contains the specific amino acids composition recited in the claim, namely isoleucine and threonine with a content of amino acids other than tryptophan, threonine, methionine and isoleucine of no more than 60 wt%. This can hardly be regarded as the most natural and common

daily activity. But most importantly, and contrary to the situation in T 2275/18, it is not possible to carry out the method of present claim 11 on a subject which is neither in a pathological state nor likely to develop one, because claim 11 precisely defines the subject as an elderly suffering from or likely to develop symptoms of frailty.

1.4.1 Considering that the prophylaxis or improvement of frailty leads at least to the maintenance of health in the elderly patient according to the patent itself, no distinction can be drawn between a therapeutic use and a non-therapeutic use, even in the context of the further limitation to the symptoms defined in claims 11-18. Even if these symptoms (decrease in walking speed, decrease in the amount of physical activity and loss of motivation) may not necessarily be as such constitutive of an illness, the prophylaxis or improvement of these manifestations of frailty necessarily aims at maintaining health.

1.5 The consequences of the above finding may be assessed under different provisions of the EPC.

Since present claims 11 and 17 concern a use which is necessarily therapeutic (i.e. at least prophylactic), the exclusion from patentability of methods for treatment of the human or animal body by therapy under Article 53(c) EPC also applies to the subject-matter of claims 11 and 17, despite the introduction of the disclaimer "non-therapeutic".

Additionally, in both T 1635/09 (see point 5 of the reasons, last paragraph) and in T 767/12 (see point 2.), a disclaimer intended to restrict the claim to "non-therapeutic" methods was in analogous situations

considered unallowable for lack of clarity under Article 84 EPC since it rendered the scope of the claim void. This is however a condition for allowing undisclosed disclaimers according to G 1/03 (see Headnote, point 2.4). Considering also that, in the present case, the undisclosed disclaimer "non-therapeutic" contradicts the original disclosure according to which the prophylaxis or improvement of frailty aims at maintaining health (see 1.3 above), this undisclosed disclaimer is also considered to infringe Article 123(2) EPC.

1.6 Considering that each of the auxiliary requests 1-29, 17A-20A and 25A comprises a claim corresponding to claim 11 or 17 of the main request, directed at the non-therapeutic use of an agent, or food or drink, for the prophylaxis or improvement of frailty, the same conclusion must be drawn for these auxiliary requests also.

2. Auxiliary requests 30, 31 - Article 123(2) EPC

In both auxiliary requests 30 and 31, claim 1 relates to an agent for use in the prophylaxis or improvement of frailty, comprising isoleucine, threonine, tryptophan and methionine as active ingredients (these 4 amino acids are hereinafter referred to as (1)-(4), see paragraph [0015] of the application as filed D16). Claim 1 further specifies in both requests that the agent is free of an amino acid other than (1)-(4).

The appellant - proprietor indicated paragraph [0053] of the application as filed (D16) as basis for the feature "free of" amino acids other than (1)-(4).

However, this passage of the application as filed discloses embodiments wherein the agent is:

- "free of amino acids other than isoleucine and threonine",
- "free of amino acids other than isoleucine, threonine and tryptophan", or "free of amino acids other than isoleucine, threonine and methionine", or
- "substantially free of amino acids other than (1) - (4)".

The same passage further defines that "Being substantially free means that the object and effect of amino acids (1) - (4) are not influenced".

The expression "substantially free " is also used in claim 7 as well as embodiment [7] in paragraph [0012] of the application as filed.

Claim 1 of auxiliary request 30 thus differs from paragraph [0053] of the application as filed by the deletion of the term "substantially".

The question under Article 123(2) EPC is whether the amendment remains within the limits of what a skilled person would derive directly and unambiguously from the the application as filed as a whole. Whether the deletion of "substantially" introduces added subject-matter can only be answered having regard to the particular disclosure of the application as filed in the case at hand.

The Board concurs with the appellant - opponent that the different expressions used in paragraph [0053] for the absence of amino acids other than two or three of (1)-(4) ("free") and for the absence of amino acids other than the four (1)-(4) ("substantially free") suggests that these expressions are not intended to mean the same thing. Furthermore, the definition given

immediately after in the same passage for the expression "substantially free" does not mention the possibility that the agent be (completely) free of amino acids other than (1)-(4), but only requires that the "object and effect" of amino acids (1)-(4) are not influenced.

In such particular circumstances, the Board does not accept the appellant - proprietor's argument that "free" should be understood as a synonym for, or even an preferred embodiment of, "substantially free". Contrary to the view expressed in the appealed decision (see §4.2.4), a person skilled in the art would not interpret the term "substantially free" as having the same meaning as the term "free".

In the Board's opinion, the examples of the application as filed cannot lead to a different conclusion. Firstly, in several of the examples, the agent is not free of amino acids other than (1)-(4) but contains additionally cystine (see tables 16 and 20). Secondly, the other examples wherein the agent is apparently free of amino acid other than (1)-(4) are specific compositions which do not necessarily illustrate the specific "substantially free" embodiment of paragraph [0053] and can in any case not overrule the explicit definition given in this paragraph in a general context.

Accordingly, auxiliary requests 30 and 31 both infringe Article 123(2) EPC.

3. Auxiliary requests 32, 33 - admittance
- 3.1 Auxiliary requests 32 and 33 were filed during the oral proceedings before the Board, and correspond to

auxiliary requests 30 and 31, wherein in claim 1 the expression "free" is replaced with "substantially free".

- 3.2 Under Article 13(2) RPBA, auxiliary requests 32 and 33 shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

In the Board's view, no such exceptional circumstances are apparent here.

The objection of added subject-matter against the expression "free" had been raised during the first instance proceedings and briefly addressed in the appealed decision (see §4.2.2 and §4.2.4). The same objection was repeated at the beginning of the appeal proceedings in the appellant - opponent's reply dated 28 March 2023 (see the paragraph bridging pages 6 and 7).

The Board's preliminary view put forward in the communication under Article 15(1) RPBA dated 4 December 2023 did not contain any new objection in this respect. The Board's finding of added subject-matter regarding auxiliary requests 30 and 31 at the oral proceedings can in these circumstances not be regarded as an exceptional circumstance. As recalled in the Case Law of the Boards of Appeal (10th edition, 2022, V.A.4.5.6.h), the very purpose of appeal proceedings is to review the contested decision. The fact that, in its communication under Article 15(1) RPBA 2020 or at the oral proceedings, the board comes to a different conclusion from the opposition division is not considered an exceptional circumstance within the meaning of Article 13(2) RPBA 2020.

- 3.3 Furthermore, in addition to Article 13(2) RPBA, the admittance of auxiliary requests 32 and 33 is also subject to the provision of Article 13(1) RPBA, which requires among other criteria that the amendment, *prima facie*, overcomes the issues raised and does not give rise to new objections. The re-introduction of the expression "substantially" is *prima facie* questionable under Article 84 EPC, in particular if the definition provided in the description (see paragraph [0053]) and based on ill-defined "object and effect" of amino acids (1)-(4) is taken into account.
- 3.4 Accordingly, the Board did not admit any of auxiliary requests 32 and 33.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated