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**Datasheet for the decision
of 14 January 2025**

Case Number: T 2380/22 - 3.3.09

Application Number: 14761548.8

Publication Number: 3043658

IPC: A23L33/10, A23L33/15, A23C9/20,
A23L33/00, A61K31/593

Language of the proceedings: EN

Title of invention:

NUTRITIONAL COMPOSITION HAVING LIPOPHILIC COMPOUNDS WITH
IMPROVED SOLUBILITY AND BIOAVAILABILITY

Patent Proprietor:

Abbott Laboratories

Opponent:

N.V. NUTRICIA

Headword:

Nutritional composition/ABBOTT

Relevant legal provisions:

EPC Art. 100(c), 100(b), 100(a), 54, 56

Keyword:

Grounds for opposition - added subject-matter (no)



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Case Number: T 2380/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 14 January 2025

Appellant:

(Opponent)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 5 August 2022
rejecting the opposition filed against European
patent No. 3043658 pursuant to Article 101(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 opponent (appellant) against the opposition division's decision to reject the opposition.

II. In its notice of opposition, the opponent requested that the patent be revoked under Articles 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

III. The following documents are relevant to the present decision:

D1: WO 2010/114627 A1

D2: WO 2004/026294 A1

D3: US 4,262,017

D4: US 4,519,961

D5: WO 2011/008097 A1

D9: Experimental report by the patent proprietor

IV. Claim 1 of the patent as granted (main request) is relevant to the present decision. It reads as follows:

"A nutritional composition having at least one protein, at least one fat, and at least one lipophilic compound, the composition comprising:

an activated assembly comprising at least one hydrophobic protein having a grand average of hydropathicity index (GRAVY) value of -0.5 to 0, at least one combination of monoglycerides and diglycerides ("MDG") and at least one lipophilic compound,

wherein the nutritional composition, after centrifugation at 100,000 x g for 1 hour at 20°C, comprises MDG in the aqueous phase that is at least 1% by weight of the total MDG in the nutritional composition."

V. The appellant argued that the amendments in claim 1 as granted which replace the term "remains" with "comprises" and define the hydrophobic protein by the GRAVY value were not allowable. The disclosure of claim 1 as granted was insufficient because the term "activated assembly" had a broad meaning and the patent failed to give guidance on how to implement this feature across the whole scope. The subject-matter of claim 1 was not novel over, or was obvious in view of, the disclosure of documents D1 to D5.

VI. The patent proprietor (respondent) argued that the amendment in claim 1 as granted did not change the scope and meaning of the claim. As regards the GRAVY value, claim 1 as granted was a simple combination of claims 1 and 11 of the application as filed. The objection of lack of sufficiency of disclosure had not been raised before and should not be admitted on appeal. Moreover, the patent set out how to make the activated assembly. As for novelty and inventive step, the appellant did not explain why, in its opinion, the opposition division's decision was incorrect.

VII. Final requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of auxiliary request 1 (filed during the opposition proceedings).

Reasons for the Decision

1. *Article 100(c) EPC*

1.1 The appellant argued that the amendments in claim 1 as granted were not allowable for the following reasons.

- Claim 1 as granted stated that the nutritional composition "comprises" MDG (a combination of monoglycerides and diglycerides) in the aqueous phase after centrifugation in a specified amount. In claim 1 of the application as filed, the term used was "remains", which implied that the amount of MDG before and during centrifugation was higher.
- The comparative formula in the experimental report D9 indicated "that there is the possibility that there is additional MDG after centrifugation". This showed that the concentration of MDG before and during centrifugation influenced the scope of the claim.
- Claim 1 as granted did not exclude the nutritional composition comprising further MDG, i.e. not only in the activated assembly. It encompassed a composition, in which 100% of the MDG was in the aqueous phase before centrifugation and only 1% after centrifugation.

- 1.2 The appellant's arguments are not convincing.
 - 1.2.1 From a technical point of view, there is no reason to believe that MDG of the activated assembly of claim 1 of the application is in the aqueous phase. The activated assembly is disclosed as a combination of MDG, a hydrophobic protein and a lipophilic compound. The ingredients disclosed in association with MDG are all hydrophobic.
 - 1.2.2 The appellant's argument based on D9 is not relevant. This document relates to experiments conducted a long time after the application's filing date. The comparative formula of D9 is not part of the disclosure of the invention and is simply not relevant when examining whether the amendment is directly and unambiguously disclosed in the application as filed.
 - 1.2.3 The interpretation of the term "remains" imposed by the application as filed is that the amount of MDG in the aqueous phase after centrifugation is what counts, regardless of what the situation might have been before or during centrifugation. For instance, example 58 of the application as filed confirms that what is relevant is solely the amount of MDG in the aqueous phase that is established after centrifugation.
 - 1.2.4 There is no indication in the application as filed that there might be an amount of MDG that was in the aqueous phase prior to centrifugation. The appellant's argument is based on speculation. The disclosure of the application as filed does not indicate that the skilled person would have understood the term "remains" in the context of claim 1 of the application as filed as meaning anything other than "comprises".

- 1.2.5 To conclude, there is no reason to deviate from the opposition division's assessment that replacing the term "remains" with "comprises" does not add subject-matter.
- 1.3 As regards the definition of the hydrophobic protein ("GRAVY value"), the appellant contested that claim 1 as granted was a combination of claims 1 and 11 of the application as filed. In the appellant's view, claim 1 as granted was directed to two or more hydrophobic proteins having the GRAVY value of claim 1.
- 1.4 This is not convincing.
 - 1.4.1 Claim 1 of the application as filed discloses that the activated assembly comprises at least one hydrophobic protein. Claim 11 of the application as filed discloses that the assembly comprises a hydrophobic protein having the specified GRAVY value.
 - 1.4.2 The appellant's argument is apparently based on the (incorrect) understanding that the expression "comprising at least one hydrophobic protein" in claim 1 as granted has a different meaning from that in claim 1 of the application as filed. This is not the case. Claim 1 as granted comprises at least one hydrophobic protein having the specified GRAVY value, but there is no indication as to whether further proteins are also part of the nutritional composition and what their features might be. In short, the amendment in claim 1 as granted which adds the GRAVY value is directly and unambiguously derivable from the combination of claims 1 and 11 of the application as filed.

1.5 The ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

2. *Article 100(b) EPC*

2.1 The appellant contested the opposition division's conclusion that the invention set out in claim 1 was sufficiently disclosed. The appellant argued that the opposition division failed to evaluate the meaning of an "activated assembly". In the appellant's view, the term was broad and the patent failed to give guidance on how to implement this feature across the whole scope.

2.2 Considering that this objection is not convincing in substance, it is not expedient to assess whether it had even been raised during the opposition proceedings and whether it is admissible on appeal.

2.3 The reader of the patent understands, in light of paragraph [0063], what an "activated assembly" is. At the same time, all features of claim 1 have to be fulfilled: the ingredients of the assembly comprise a hydrophobic protein having the specified GRAVY value. The issue of whether there is an activated assembly is confirmed by the centrifugation test of claim 1. In addition, methods for preparing the activated assembly are set out in the patent. For this purpose, the activated premix of paragraphs [0129] and [0130] or the variations in paragraphs [0221] to [0230] may be used.

2.4 To conclude, the patent and in particular its claim 14 disclose at least one way to carry out the invention. There is no evidence that the skilled person would face an undue burden in carrying out the invention. Therefore, the ground for opposition under

Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

3. *Article 100(a) EPC - novelty*

3.1 The appellant contested the opposition division's conclusion that claim 1 was novel. In essence, the appellant maintained its view presented during the opposition proceedings that documents D1 to D5 (implicitly) disclosed all features of claim 1.

3.2 Apart from stating that claim 1 did not require a premix, the appellant has not addressed the opposition division's reasoning on novelty. However, the decision under appeal gives further, valid reasons that show why the subject-matter of claim 1 is novel.

3.3 The opposition division correctly concluded that documents D1 to D5 did not disclose compositions that pass the centrifugation test of claim 1. There was no conclusive evidence that this feature was implicitly fulfilled in D1 to D5, let alone that an activated assembly was formed in D1 to D5. Furthermore, none of documents D1 to D5 disclosed a protein having the GRAVY value of claim 1.

3.4 No reason can be seen to review the opposition division's conclusions. Therefore, the ground for opposition under Articles 100(a) and 54 EPC does not prejudice the maintenance of the patent as granted.

4. *Article 100(a) EPC - inventive step*

4.1 The appellant contested the opposition division's conclusion that claim 1 involved an inventive step. Here again, as for novelty, the appellant's essential

criticism was that the opposition division referred to a premix, although claim 1 did not require a premix.

- 4.2 However, claim 1 involves a nutritional composition involving an activated assembly which is identified by the centrifugation test. Clearly, the opposition division is referring to this assembly, in line with the (preferred) disclosure throughout the patent, when it speaks of a premix.
- 4.3 As the opposition division correctly explained, the patent shows that the specific association of components set out in claim 1, i.e. the activated assembly, allows the provision of the lipophilic compounds "in a more soluble form", which provides an improved bioavailability of the lipophilic compound. The solution of claim 1 was not suggested in the art.
- 4.4 The appellant argued that it would have been obvious to provide an alternative nutritional composition by mixing the lipophilic compound with the amphiphilic MDG in a first step before adding water in a second step. However, the appellant did not explain which disclosure in the prior art would have led the skilled person to conclude that such a sequence of steps was obvious. Furthermore, the appellant did not explain why using a protein with the GRAVY value of claim 1 would have been a trivial modification.
- 4.5 To conclude, no reason can be seen to set aside the opposition division's assessment of inventive step. The ground for opposition under Articles 100(a) and 56 EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated