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Datasheet for the decision of 25 September 2013

Case Number: T 0547/09 - 3.3.07

Application Number: 00125893.8

Publication Number: 1106174

IPC: A61K9/50, A61K9/51, A61K9/16

Language of the proceedings: EN

Title of invention:
Compositions containing fat-soluble vitamins

Patent Proprietor:
DSM IP Assets B.V.

Opponent:
ADISSEO FRANCE

Headword:
Compositions containing fat-soluble vitamins/DSM IP Assets

Relevant legal provisions:
EPC Art. 54, 56, 100(b)
RPBA Art. 13

Keyword:
Main request, inventive step (no)
Auxiliary request 1, admission into proceedings (yes), sufficiency of disclosure (yes), inventive step (yes)

Decisions cited:

Catchword:

Beschwerdekammern
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Case Number: T 0547/09 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 25 September 2013

Appellant: (Opponent)	ADISSEO FRANCE 42 Avenue Aristide Briand 92160 Antony (FR)
Representative:	Guerre, Dominique Cabinet Germain et Maureau 12 Rue Boileau B.P. 6153 69466 Lyon Cedex 06 (FR)
Respondent: (Patent Proprietor)	DSM IP Assets B.V. Het Overloon 1 6411 TE Heerlen (NL)
Representative:	Teipel, Stephan Lederer & Keller Patentanwälte Unsöldstrasse 2 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 December 2008 concerning maintenance of the European Patent No. 1106174 in amended form.**

Composition of the Board:

Chairman: J. Riolo
Members: D. Boulois
P. Schmitz

Summary of Facts and Submissions

I. European patent No. 1 106 174 based on application No. 00 125 893.8 was granted on the basis of a set of 17 claims.

II. Opposition was filed against the granted patent. The patent was opposed under Article 100(a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step and the patent was not sufficiently disclosed.

III. The documents cited during the opposition and appeal proceedings included the following:
(1) WO 99/42134
(2) FR 2 281 961
(4) "Pharmacie Galénique, Bonnes pratiques de fabrication des Médicaments", A. Le Hir, 7th edition, 1997, pages 64-68, 149-156
(5) EP 966 889

IV. The appeal by the opponent lies from the decision of the opposition division to maintain the patent as amended. The decision was based on the main request filed with letter dated 23 October 2006.

Independent claim 1 read as follows:
"1. Powder composition which comprises at least one fat-soluble vitamin characterized in that said vitamin is dispersed in a matrix of a natural polysaccharide gum or a mixture of said gums having an emulsifying capacity and/or a protein or a mixture of proteins having an emulsifying capacity, and wherein said fat-soluble vitamin is present in said powder composition in the form of droplets having an average diameter within the range of about 70 to about 120 nanometres

(nm), wherein the ratio of fat soluble vitamin to matrix component is from about 1:8 to 1:1".

V. According to the decision under appeal, the opposition division considered that, in the light of the examples, the skilled person was able to produce the claimed compositions without undue burden. The requirements of sufficiency of disclosure were met.

As regards the novelty of the main request, documents (1), (2) and (5) were discussed.

As regards inventive step, document (2) was considered as starting point for the assessment of inventive step. The claimed subject-matter differed in the presence of a vitamin.
The underlying problem was seen as additionally delivering fat-soluble vitamins in the form of clear aqueous solutions. This was not predictable, and the subject-matter of claim 1 involved an inventive step over document (2).

Document (5) could also be seen as starting point for the assessment of inventive step.
The subject-matter of claim 1 differed in the particle size, and here the problem was seen as the provision of a clearer solution. There was no motivation to combine document (5) with the teaching of document (2). Thus inventive step was acknowledged over document (5).

VI. The opponent (appellant) filed an appeal against the decision of the opposition division.

VII. In reply to the statement of grounds of appeal, the patent proprietor (respondent) requested as a main

request that the appeal be dismissed; alternatively it submitted seven auxiliary requests.

VIII. In a communication sent in preparation for oral proceedings, the board gave its preliminary non-binding opinion, in particular on novelty and inventive step. It noted in particular that the main request and auxiliary requests 1-3 were considered novel but not inventive, while auxiliary request 4 appeared to be inventive over the prior art.

IX. With letter dated 23 August 2013, the appellant informed the board that it would not attend the oral proceedings.

X. With letter dated 23 August 2013, the respondent submitted an amended main request and seven auxiliary requests. It additionally submitted a letter dated 13 May 2003, which had already been filed before the department of first instance, and comprising technical experiments.

Claim 1 of the main request read as follows:

"1. Powder composition which comprises at least one fat-soluble vitamin characterized in that said vitamin is dispersed in a matrix of a natural polysaccharide gum or a mixture of said gums having an emulsifying capacity and/or a protein or a mixture of proteins having an emulsifying capacity, and wherein said fat-soluble vitamin is present in said powder composition in the form of droplets having an average diameter within the range of 70 to 120 nanometres (nm), wherein the ratio of fat-soluble vitamin to matrix component is from 1:8 to 1:1."

XI. Oral proceedings took place on 25 September 2013 in the presence of the respondent.
A new auxiliary request 1 was submitted during oral proceedings.

Claim 1 of auxiliary request 1 read as follows:

"1. Powder composition which comprises at least one fat-soluble vitamin characterized in that said vitamin is dispersed in a matrix of a natural polysaccharide gum or a mixture of said gums having an emulsifying capacity and wherein said fat-soluble vitamin is present in said powder composition in the form of droplets having an average diameter within the range of 70 to 120 nanometers (nm), wherein the ratio of fat-soluble vitamin to matrix component is from 1:8 to 1:1."

XII. The arguments that the appellant-opponent submitted in writing, as far as relevant for the present decision, may be summarised as follows:

As regards the main request, document (1) or (2) was considered the closest prior art.
The substitution of the carotenoid of document (2) by a fat-soluble vitamin did not necessitate any incitation for a skilled person, since these actives were generally known to be systematically associated. The teaching of document (2) could also be associated with either of document (5) or (4) to arrive at the conclusion of lack of inventive step in the main request.
Claim 1 was also not inventive in view of the combination of document (1) with document (4).

As regards the subject-matter of dependent claim 2 of the main request, which concerned the use of a polysaccharide gum as matrix component, the gums were known from document (4) to be emulsifiers and protective colloids for emulsions, and for that reason the choice of these substances could not be considered inventive.

No comments were submitted regarding the auxiliary requests.

XIII. The arguments of the respondent-proprietor, as far as relevant for the present decision, may be summarised as follows:

As regards the main request, document (5) could be seen as the closest prior art, especially examples 1, 3 and 6.
The difference between the claimed subject-matter and this teaching was the diameter of the fat-soluble vitamin droplets. Two effects could thus be identified, namely the achievement of optical clarity in a liquid comprising the claimed powder, in particular with high concentrations of vitamins, and the absence of ringing or phase separation in the same liquid.
Figure 2 of the patent showed the link between fat droplet size and optical turbidity. A NTU of less than 20 units could be obtained with a fat droplet size of 70 to 120 nm.
Example 1 of the patent in suit showed a fat droplet size of 140 nm, which was slightly more than the claimed droplet size, but served as an indication that the effect was achieved with a lower droplet size.
The problem could thus be identified as the provision of a powder composition of fat-soluble vitamins which can be added to beverages without affecting the optical

clarity of the beverage to which it is added and without causing phase separation.
The effects were shown by examples 1 and 2 and figure 2 of the patent in suit.
The teaching of document (5) did not mention any of these problems, in particular not that a diminution of the size of the fat droplets would decrease the turbidity.
A modification of the teaching of document (5) to arrive at the claimed subject-matter was not conceivable or obvious. Moreover, the production of fat droplets of this size involved special technical means and processes, different from those used in document (5), which would be unable to produce such size of emulsion droplet.

XIV. The appellant (opponent) requested in writing that the decision under appeal be set aside and the patent be revoked.

XV. The respondent (patent 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 letter dated 23 August 2013 or of auxiliary request 1 filed during the oral proceedings before the board.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - Inventive step

2.1 The present invention relates to powder compositions comprising fat-soluble vitamins and a matrix component

which can be added to beverages to produce vitamin-supplemented beverages. The powder composition of fat-soluble vitamins does not affect the optical clarity and sensory properties of the beverage to which it is added, i.e. the beverage should not appear significantly more turbid on visual inspection (see paragraphs [0003], [0040]). The most important variable for providing this acceptable turbidity is the droplet size of the fat-soluble vitamin (see paragraph [0067]), while the matrix component must be able to produce an emulsion which remains stable (see paragraph [0016]).

The powder composition as claimed in claim 1 of the main request comprises at least one fat-soluble vitamin present in said composition in the form of droplets of an average diameter of 70 to 120 nanometres and dispersed in a matrix of polysaccharide gum or a protein in a ratio of vitamin to matrix component from 1:8 to 1:1.

2.2 The appellant cited documents (1) and (2) as closest prior art, while the opposition division additionally considered document (5).

Document (1) discloses tablettable spray-dried compositions of gelatin and oil, which can be selected from vitamins, flavours or fragrance oils. The size of the oil particles is lower than 0.8 µm, and the amounts of oil and gelatin are respectively 40-90% and 10-60%. The examples of this document show compositions having oil particle sizes greater than 0.25 µm and a weight ratio different from the claimed weight ratio.

Document (2) relates to powder preparations comprising a carotenoid with a particle size lower than 0.1 µm and sodium lauryl sulphate as emulsifier, which can easily be dispersed in water solutions and form clear and

coloured solutions. Examples 2 and 3 show compositions which have the claimed ratios and which reconstitute a clear beverage.

Document (5) discloses cold-water-dispersible powder compositions of fat-soluble substances, such as fat-soluble vitamins, and a protective colloid of gelatin enveloping said substance; the composition is stable when dispersed in cold water and has a mean particle size equal to or less than 0.6 µm in diameter (see claim 1). Examples 1 and 3 show compositions of vitamin A and gelatin, in the weight ratios claimed by the present invention, having an average particle size of respectively 0.6 and 0.28 µm. Example 6 shows the preparation of compositions comprising a fat-soluble vitamin having a droplet size of 0.18 µm.
This document does not explicitly disclose compositions having an average droplet size of the fat-soluble vitamin of 70 to 120 nanometres.

The document presenting most common technical features with the claimed subject-matter of claim 1 of the main request is document (5). The board concludes therefore that this document constitutes the closest prior art.
This choice was agreed to by the respondent during oral proceedings.

2.3 According to the respondent, the problem of the claimed invention is the provision of a powder composition of fat-soluble vitamins which can be added to beverages without affecting the optical clarity and without causing phase separation in the beverage to which it is added.

2.4 The solution is the powder composition according to claim 1 with in particular an average diameter of the fat-soluble vitamin droplet of 70 to 120 nm.

2.5 It has to be investigated whether there is sufficient evidence supporting the alleged effects.

2.5.1 The board observes that the distinguishing feature, namely the average fat droplet diameter, cannot be considered to solve the problem of phase separation.
The only feature of claim 1 of the main request which can be identified as responsible for an absence of phase separation is in fact the matrix component having an emulsifying capacity. This matrix component must be such as to emulsify the oil into a fine dispersion in an aqueous medium and to be capable of forming and maintaining a stable emulsion of the desired droplet size, in other words able to avoid phase separation (see paragraphs [0015] and [0016]).
Moreover the problem of phase separation had already been solved in the closest prior art by the same technical feature as in the present invention. The powders disclosed in document (5) do indeed also provide a stable emulsion when dispersed in cold water (see col. 2, l. 34-38; claim 1), due to the presence of gelatin which serves as emulsifier and as protective colloid for fat-soluble vitamin droplets of a size less than 0.6 µm (see col. 2, l. 39-41). This document thus explicitly shows that gelatin was capable of producing stable emulsions of fat-soluble vitamins with a droplet size below 0.6 µm.
Consequently, the problem of avoiding phase separation cannot be considered in the assessment of inventive step of the subject-matter of claim 1 of the main request over document (5).

2.5.2 As regards the optical clarity of the beverage, the description of the patent in suit explains that an optically clear liquid to which a powder composition according to the invention has been added must preferably have a resulting NTU of no more than 40 units, preferably 10 to 20 NTU units (see par. [0014] of the description).

Figure 2 of the patent illustrates the relationship between the droplet size and the optical clarity of a beverage comprising the powder.
This figure shows that the optical clarity depends on the concentration of the fat-soluble vitamin in the final beverage, and on the size of the droplets. Optical clarity improves with diminishing droplet size, and worsens with vitamin concentration.
The curve disclosed in Figure 2 thus shows that a fat droplet size of 70-120 nm will induce a turbidity of less than 20 NTU, at fat-soluble vitamin concentrations of 15% and 25% in the water dispersion. An extrapolation of the curve shown in Figure 2 tends also to show that particles with an average size such as shown in example 3 of document (5), namely up to 280 nm, will produce a NTU of around 40.

In view of Figure 2, it is credible that the selection of the claimed size range does not affect the optical clarity and sensory properties of a beverage to which it is added. It is also credible that the optical clarity of the beverage resulting from the addition of the powder is dependent on the size range of the droplets of the fat-soluble vitamins and improves as the size of the droplets diminishes.

The examples and Figure 2 of the description thus establish the credibility of the presence of an

improvement as regards optical clarity vis-à-vis the closest prior art.

2.5.3 The problem underlying the patent in suit in the light of document (5) is thus the provision of a powder composition of fat-soluble vitamins which can be added to beverages without affecting the optical clarity of the beverage to which it is added.

2.6 The question to be answered is whether the proposed solution would have been obvious to the skilled person in the light of the prior art.

Document (4) is a document of common general knowledge which shows that the macroscopic appearance of an emulsion improves when the fat droplet size decreases (see page 156, Table XX). The emulsions become slightly translucent when the droplet size is between 1 µm and 100 nm, and significantly translucent from 100 nm. This knowledge is further illustrated by the teaching of document (2), which shows that the incorporation of carotenoids of a droplet size of less than 100 nm will produce an optically clear beverage (see page 2, l. 12-15; example 2).

Having regard to the prior art, it was thus obvious for the skilled person, seeking to improve the optical clarity of a beverage to which a powder of fat-soluble vitamins is added, to provide the fat-soluble vitamins in the form of droplets of a certain size.
The choice of the claimed droplet size, namely a droplet size of 70-120 nm, appears obvious for the skilled person, and the subject-matter of claim 1 of the main request is not inventive.

2.7 Further arguments from the respondent

According to the respondent, the teaching of document (5) does not relate to the problem of optical clarity, and does not give any indication that diminution of the fat droplet size would influence this parameter. This document therefore does not provide any incentive to modify the droplet size or more generally to improve the optical clarity of the solution.
Moreover, the obtention of a fat droplet size as claimed is technically impossible using the process of preparation disclosed in document (5). The respondent quoted a study provided during the examination phase before the department of first instance proving that, with the equipment used in the preparation of the formulations of document (5), it was not possible to obtain vitamin droplets with an average diameter of the claimed range. According to these experiments, the present invention for the first time provided a powder composition comprising vitamin droplets having the claimed diameter range.

The board could however not follow these arguments. It is indeed true that document (5) provides no incentive either to influence the optical clarity of the beverage resulting from the dissolution of the vitamin powder or to select a particular size range. It remains that the droplet diameter disclosed in document (5) is 0.6 µm or less, and that the selection of any sub-range must provide a technical effect which was unexpected to the skilled person. This is not the case for the selected average droplet diameter, for which an improvement in optical clarity was commonly known and expected as shown by document (4). In such a case, there does not need to be any incentive in the prior art to take the step defined as the difference between the closest prior art and the subject-matter of the opposed patent.

It is enough that this step is generally and commonly known to the skilled person.
As regards the suitability of the process for making vitamin droplets in document (5), the board notes that the process is not the subject of this document.
Moreover, documents (4) and (2) show that methods for the preparation of fat droplets of a very low size were commonly known at the filing date of document (5). It would thus have been possible for the skilled person to use such alternative known methods to obtain fat particles of the desired size.

2.8 Consequently, the main request does not meet the requirements of Article 56 EPC. Under these circumstances, this request must be rejected, and there is no need to discuss further objections.

3. Auxiliary request 1

3.1 Admission of auxiliary request 1 into the proceedings

Auxiliary request 1 was filed during oral proceedings and is based on auxiliary request 4 filed in response to the statement of grounds of appeal of the appellant-opponent.
This new request was filed as a direct response to objections under Rule 80 EPC and Article 123(3) EPC raised by the board for the first time during oral proceedings against auxiliary request 4. It differed from auxiliary request 4 in the suppression of dependent claims and in a feature violating the requirements of Article 123(3) EPC.
The amendments made to the request are occasioned by developments during the appeal proceedings and *prima facie* address the issues raised by the board without giving rise to new ones and without adding complexity

to the case under consideration. They constitute a direct, clear and fair attempt to respond to the board's objections. Therefore, auxiliary request 1 is admitted into the proceedings (Article 13(1)(3) RPBA).

3.2 Article 100(b) EPC

Since this ground of opposition has not been further argued or discussed in the appeal phase, the board sees no reason to depart from the conclusions of the department of first instance.

3.3 Novelty

This request is based on auxiliary request 4 filed with letter dated 23 August 2013. The novelty of this request has never been contested by the appellant.
The board notes that the only document cited for novelty in the appeal phase was document (1), which does not refer to a natural polysaccharide gum or a mixture of said gums.
Consequently, auxiliary request 1 meets the requirements of Article 54 EPC.

3.4 Inventive step

3.4.1 The subject-matter of claim 1 of auxiliary request 1 differs from that of the main request in the restriction to a natural polysaccharide gum or a mixture of said gums having an emulsifying capacity as matrix component.

3.4.2 Document (5) remains the closest prior art. This document does not disclose compositions having an average droplet size of the fat-soluble vitamin of 70 to 120 nanometers. Moreover, the compositions disclosed

in this document comprise as matrix component a protein, namely gelatin, and not a natural polysaccharide gum or a mixture of said gums.

3.4.3 The description of the patent comprises three examples in which the average droplet size is said to be less than 140 nm, which is higher than the claimed size.

Example 1a discloses a spray-dried powder of vitamin E acetate dispersed in a matrix of gum arabic in the claimed weight ratio. When this powder was used in a beverage, the turbidity of the beverage did not increase significantly and no phase separation occurred (see paragraph [0078]).

Examples 2 and 3 used the formulations of example 1 to prepare effervescent tablets and conditioning shampoo respectively.

Although the droplet size of the fat-soluble vitamin of the examples is higher than the claimed size range, it remains credible that a powder composition having a fat droplet size lower than the size below 140 nm of the examples and a matrix component chosen from gum arabic will not induce any phase separation or instability of the emulsion.

3.4.4 The problem underlying the patent in suit in the light of document (5) is thus the provision of an alternative powder composition of fat-soluble vitamins which can be added to beverages without affecting the optical clarity of the beverage to which it is added and without causing phase separation.

3.4.5 There is no hint or disclosure in the cited prior art relating to the use of a polysaccharide gum for the manufacture of powders or beverages with fat-soluble vitamin droplets of the claimed size.

The emulsifying properties of some polysaccharide gums were known from document (4) (see page 151). This document however relates neither to the manufacture of emulsions with particular oils, such as fat-soluble vitamins, nor to the preparation or stabilisation of emulsions having a large surface area, such as emulsions with fat droplets having an average size of 70 to 120 nm.
Moreover, the structure and the physical and chemical properties of a polysaccharide gum being very remote from those of a protein such as gelatin which is used in document (5), a skilled person would not consider a polysaccharide gum as an immediate and obvious alternative to a protein.

It was thus not predictable that a polysaccharide gum would have sufficient emulsifying properties to emulsify this particular oil into a fine dispersion of the desired size droplets of 70 to 120 nm under conditions of high-pressure homogenization, and would also be capable of reconstituting an emulsion from the powder form and maintaining the said emulsion (see paragraphs [0015] and [0016]).

Therefore the solution proposed by the subject-matter of claim 1 as regards the matrix component constitutes a non-obvious alternative to the teaching of document (5).

3.5 Auxiliary request 1 therefore meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the claims of auxiliary request 1 filed during the oral proceedings before the board and a description yet to be adapted thereto.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated