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**Datasheet for the decision
of 23 September 2008**

Case Number: T 1418/05 - 3.3.09

Application Number: 97912096.1

Publication Number: 0929235

IPC: A23L 1/302

Language of the proceedings: EN

Title of invention:

Process for preparing an optically clear vitamin supplement

Patentee:

DSM IP Assets B.V.

Opponent:

BASF Aktiengesellschaft

Headword:

-

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Inventive step (no)"

"Consideration of neighbouring technical fields (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1418/05 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 23 September 2008

Appellant: DSM IP Assets B.V.
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Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office orally announced
29 June 2005 and posted 20 September 2005
revoking European patent No. 0929235 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
M-B. Tardo-Dino

Summary of Facts and Submissions

I. Mention of the grant of European patent No 0 929 235 in respect of European patent application No. 97 912 096.1 filed on 2 October 1997 as International application No. PCT/EP97/05421 (published as WO 98/15195) in the name of *F. Hoffmann-La Roche AG* was announced on 19 December 2001 (Bulletin 2001/51). According to the transfer declaration dated 29 September 2003 the patent was assigned to *DSM IP Assets B.V.*

The patent, entitled "*Process for preparing an optically clear vitamin supplement*" was granted with five claims. Claim 1 reads as follows:

"1. A process for preparing an optically clear vitamin supplement comprising:

(A)

(1) a fat soluble vitamin, and

(2) an emulsifier for (1),

the ratio of (1) to (2) being from 1:1 to 1:9, and

(B) water,

wherein the ratio of (A) to (B) is from 1:1 to 1:9, which process comprises mixing the fat soluble vitamin and the emulsifier at a temperature between about room temperature and 90°C so as to form a homogeneous mixture, and mixing said mixture with water at a temperature of from 30°C to 35°C in a ratio of from 1:1 to 1:9."

Claims 2 to 4 were, either directly or indirectly, dependent on Claim 1.

II. Opposition against the patent was filed by

BASF Aktiengesellschaft

on 17 September 2002.

The opposition was based on Article 100(a) EPC in that the claimed subject-matter was not novel and did not involve an inventive step. In support of its objections, the Opponent cited the following documents:

- D1 Technisches Merkblatt der BASF AG "Vitamine in Tabletten und Lösungen - Rezeptvorschläge", Ausgabe Juli 1989;
- D2 Firmenbroschüre "Atlas Tenside für Pharmazie und Kosmetik" der Fa. Atlas Chemie GmbH, Deutschland, Ausgabe 1970, particularly page 16.

The Proprietor disputed that D1 was a suitable starting point for the consideration of inventive step and suggested that the document

D3 WO-A 95/24832,

cited as D1 in the examining procedure, be considered representative of the closest prior art, since both the patent in suit and D3 dealt with the same problem of providing clear vitamin compositions that can be added to beverages.

III. With its decision, orally announced on 29 June 2005 and issued in writing on 20 September 2005, the Opposition Division revoked the patent. The decision was based on the claims as granted and on a set of Claims 1 to 4 according to an auxiliary request filed with the letter dated 27 May 2005. Claim 1 of this claim set reads as follows:

"1. A process for preparing an optically clear vitamin supplement comprising:

(A)

(1) a fat soluble vitamin, and
(2) polyoxyethylene(20)sorbitan mono-oleate,
the ratio of (1) to (2) being from 1:1 to 1:9, and

(B) water,

wherein the ratio of (A) to (B) is from 1:1 to 1:9, which process comprises mixing the fat soluble vitamin and the polyoxyethylene(20)sorbitan mono-oleate at a temperature between about room temperature and 90°C so as to form a homogeneous mixture, and mixing said mixture with water at a temperature of from 30°C to 35°C in a ratio of from 1:1 to 1:9."

The Opposition Division held that the claimed process was novel over the cited prior art, but did not involve an inventive step in view of D1, either alone or in combination with D2. The Opposition Division did not share the Proprietor's view that D3 was the closest prior art for the assessment of inventive step and

pointed out that the claims of the patent in suit did not specifically refer to beverages.

With regard to the main request it was held that the skilled person intending to obtain clear vitamin solutions by mixing the vitamin/emulsifier blend with water would work within the temperature range given in "Rezept 2" of D1, which overlapped the claimed temperature range.

An inventive step of the process according to the auxiliary request was denied in view of "Rezept 3" of D1 in which the same emulsifier Tween 80 as required according to Claim 1 was used and account being taken of D2, indicating on page 16 that only slight warming may be needed in order to obtain optically clear vitamin solutions.

IV. On 9 November 2005 the Patent Proprietor (hereinafter: the Appellant) lodged an appeal against the decision of the Opposition Division. The Statement of the Grounds of Appeal was filed on 30 January 2006 and was accompanied by a set of Claims 1 to 4 according to an auxiliary request, which corresponded to the set of claims of the auxiliary request filed in the opposition proceedings.

The Grounds of Appeal also comprised a test report intended to demonstrate the superior properties of polysorbate 80 - the emulsifier required in Claim 1 of the auxiliary request - with regard to the reduction of the turbidity of beverages.

The Appellant also maintained its previous view that, contrary to the opinion of the Opponent (hereinafter

the Respondent), D3 and not D1 was representative of the closest prior art.

V. In the oral proceedings, which took place on 23 September 2008, the Board pointed out that, in determining the closest prior art for the assessment of inventive step, D2 should also be taken into account. In this respect the Appellant said that arguments provided in respect of D1 principally also applied to D2.

VI. Novelty was not in dispute in the appeal proceedings. Therefore, only the arguments of the parties as to inventive step are presented in the following.

VII. The arguments of the Appellant can be summarised as follows:

The Respondent's view that D1 should be considered as the closest prior art could not be accepted because this document was not concerned with vitamin supplements for beverages but pertained to vitamin solutions suitable for pharmaceutical applications, and therefore to a different technical field. According to the case law, the suitability of a document as the closest prior art did not necessarily require the maximum overlap of features but rather focussed on the relatedness of the technical fields. The skilled person would therefore not consider D1 in assessing inventive step.

The fact that the vitamin solutions according to D1 were suitable for pharmaceutical products rather than for beverages as required by the teaching of the patent

(paragraph [0005] of the patent specification) was confirmed by the possible use of emulsifiers such as Cremophor, antioxidants such as BHT or solubilizers such as Lutrol in Recipes 1 to 3 of D1 which all were not permitted for food applications.

Similarly, D2, entitled "Atlas Tenside für Pharmazie und Kosmetik", was concerned with a different technical field and could therefore not be considered representative of the closest prior art. But even if the skilled person were to contemplate D2, he would not be motivated to select the emulsifier Tween 80 required in Claim 1 of the auxiliary request from the list of numerous emulsifiers mentioned on page 16 of D2 in order to obtain the superior properties in the clarity of beverages over the emulsifiers Tween 60 and sucrose esters of fatty acids as demonstrated in the test report.

In this connection reference had to be made to the passage in the left column of page 10 disclosing that it was known to have regard to the HLB value of an emulsifier system in order to obtain optimum results. However, although Tween 80 and Tween 60 had almost the same HLB value, Tween 80 was surprisingly better in obtaining optically clear beverages. This was not obvious from D2.

Because D3 related to the same technical problem, ie. the preparation of optically clear aqueous solutions of biologically active oils for animal or human healthcare which, *inter alia*, can be added to beverages, this document was representative of the closest prior art.

It was taught in D3 that, after mixing the biologically active oil with an emulsifier, the mixture was combined with water at a minimum temperature of 95°C. In contrast thereto, according to the claimed process, a maximum temperature of 35°C was applied when mixing the vitamin/emulsifier composition with water. A skilled person starting from D3 would therefore not arrive at the claimed process.

VIII. The Respondent argued as follows:

According to the claims, the invention was exclusively defined by a two-step process comprising mixing in a first step A, the vitamin and the emulsifier in certain amounts relative to each other, and in a second step B, the composition obtained from step A with water. The claims did not contain any features relating to the addition of the resulting vitamin solution to beverages. Therefore, D1 was representative of the closest prior art because the optically clear vitamin solutions described in recipes 2 and 3 of this document resulted from process steps which corresponded to those of the claimed invention.

A skilled person would also consider pharmacy and food chemistry to be neighbouring technical fields and knew which pharmaceutical adjuvants are also permitted as additives in food compositions. Therefore he would be aware that the components "Cremophor", "Lutrol" or "BHT" used in recipes 2 and/or 3 of D1 had to be replaced by appropriate equivalent food-compatible ingredients in the case of the use of the vitamin solutions for food applications.

The skilled person would also be acquainted with the principle of preparing vitamin emulsions in the pharmacy or food area and would know that moderate temperatures had to be applied in order not to destroy the micelles in the emulsion or the heat sensitive vitamins.

Therefore, the problem to be solved by the invention was to be seen in providing an alternative method for preparing optically clear vitamin solutions. In solving this problem, the skilled person would work within the temperature range of room temperature to 65°C in which range the vitamin solutions described in recipes 1 to 3 of D1 were prepared and would find, by way of routine experiments, the optimum mixing temperature for a certain vitamin/emulsifier composition with water.

Furthermore, the test report provided with the grounds of appeal did not unambiguously demonstrate the superior properties of the emulsifier Tween 80 over Tween 60 or fatty acid sucrose esters with regard to a reduced turbidity of the vitamin-fortified beverages. It was not possible to know from these experiments whether the vitamin/emulsifier compositions had been optically clear before adding them to beverages. Rather, it appeared that the vitamin solutions with Tween 60 and fatty acid sucrose esters as emulsifiers should have been turbid. This might be concluded from the disclosure in the right column at page 16 of D2 where it was indicated that emulsifier/substrate compositions, once they are optically clear, could be infinitely diluted with water.

- IX. The Appellant requested that the decision under appeal be set aside and the patent be maintained as granted or alternatively on the basis of Claims 1 to 4 filed with the Statement of the Grounds of Appeal.

- X. The Respondent requested that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal is admissible.

- 2. *Inventive step*

- 2.1 The subject-matter of the patent in suit

According to the features defined in the claims the invention concerns a two-step process for the preparation of optically clear aqueous fat soluble vitamin/emulsifier compositions.

It is said in the description of the patent specification that the vitamins in the optically clear compositions are present in a nutritionally supplemental amount that can be added to beverages (paragraph [0005]). This purpose is reflected by the relative amounts of the vitamin, the emulsifier and water as defined in Claim 1 of the main and the auxiliary request. According to paragraph [0012] the surfactant is preferably non-ionic and is a material approved for food consumption.

The preferred emulsifier is polyoxyethylene(20)sorbitan mono-oleate, also known under the name "polysorbate 80" and commercially available as "Tween 80". This

emulsifier is mandatory according to Claim 1 of the auxiliary request.

The experimental evidence provided in the patent specification and the test report submitted with the grounds of appeal demonstrate the following:

- Fortification of optically clear beverages (like Gatorade Lemon Ice and Apple Juice with initial turbidity <10) with a non-aqueous vitamin/polysorbate 80 mixture prepared in one step according to control example 1 leads to a beverage having an enhanced turbidity >10;
- the above beverage fortified with an aqueous vitamin/polysorbate 80 composition and prepared in a two step process according to the inventive example 2 has a reduced turbidity of <10 (cf. Table 1);
- Fortification of the above beverage with an aqueous vitamin/polysorbate 80 emulsifier composition, wherein the ratio of vitamin/emulsifier (A) to water (B) is outside the claimed range of 1:1 to 1:9, also leads to a higher turbidity of the beverages (Table 2);
- Clear beverages like Gatorade Lemon Ice and Apple Juice remain clear when fortified with an optically clear vitamin/polysorbate 80 emulsifier composition prepared according to the invention. Initially turbid beverages (Gatorade Lemon Lime/Orange) remain turbid when fortified with the same clear vitamin solution (Table 4).
- The (optically clear) beverage Gatorade Lemon Ice (see above) remains clear after fortification with a vitamin/polysorbate 80 emulsion. The beverage has enhanced turbidity when fortified with an emulsion

containing polysorbate 60 or sucrose esters of fatty acids (Table of the test report dated 30 January 2006).

From the above the conclusion can be drawn that the turbidity of optically clear beverages remains low after fortification with a vitamin/polysorbate 80 solution prepared in accordance with the claimed process.

It is, however, not possible to know from the patent whether the enhanced turbidity of the comparative beverages in the test report is due to the unsuitability of polysorbate 60 or sucrose fatty ester as emulsifier for vitamins or is caused by an unsuitable vitamin/emulsifier/water mixing ratio leading to an aqueous vitamin/emulsifier solution which is turbid as such.

2.2 The closest prior art

What should be taken as the closest prior art was in dispute during the opposition and appeal proceedings (points VII and VIII). The Appellant's key argument, however, that D1 and D2 were in a different technical field (ie. pharmacy/cosmetic) and could therefore not represent the closest prior art for food applications is, in the Board's judgment, not convincing.

In this context, it must first of all be pointed out that the claimed invention is concerned with a process for preparing an optically clear vitamin solution, which means that it is the process features to which the claimed invention is essentially directed. Contrary to the appellant's contention, the intended use of such

solutions as vitamin supplement does not restrict the claim to the use of these solutions as beverage additives.

It is therefore the Board's view that a skilled person intending to find appropriate process measures for preparing such vitamin solutions would not hesitate to consider prior art relating to basic preparation techniques in technical areas closely related to the field of the production of beverages for human consumption, in particular fields also requiring health and welfare compatibility.

It cannot be disputed in this context that the applicability of vitamin preparations to the human body would have been known to the skilled person. Reference is made in this context to paragraph [0002] of the patent specification where it is stated in general that "*vitamin supplements for human and veterinary use are commonplace*". This "human/veterinary use" includes oral administration, for instance as nutritional supplements or pharmaceutical preparations, or surface applications such as cosmetic formulation.

The Board therefore concludes that a skilled person intending to prepare vitamin solutions for nutritional purposes would also consider process measures which are relevant for the preparation of pharmaceutical and cosmetic formulations and would adapt compositional details to the intended use of the resulting solution. This all the more so as the Appellant has not provided any evidence or any convincing arguments that process measures for the preparation of pharmaceutical/cosmetic vitamin solutions according to D1 or D2 would not be

applicable to the preparation of formulations in which the vitamin/emulsifier composition has to fulfil nutritional-specific standards.

The Appellant's attempt, relying on the fact that certain additives used in the documents are not permitted in the food industry, to construct a prejudice against the use of D1 or D2 as closest prior art, is also not successful. As set out in paragraph [0012] of the patent specification, where it is stated that "... *the emulsifier should be GRAS ... or an approved material for food consumption as determined by the various regulatory agencies world wide*", the skilled person is not only aware of restrictions for certain additives but also has access to information allowing him to routinely substitute for substances, eg emulsifiers, not permitted in foods, other appropriate substances which are permitted for nutritional purposes.

For these reasons D1 and D2, lying in the field of pharmacy/cosmetics, constitute relevant prior art for the consideration of inventive step of the claimed process and have therefore to be taken into account in determining the closest prior art.

From D2 it is known that certain hydrophilic emulsifiers have the property of making a number of water insoluble components water soluble. Vitamin oils are disclosed as one group of insoluble components. Suitable emulsifiers are, inter alia Tween 20/60 and 80; cf page 16, paragraph 4), left column. In the right column of page 16 a two-step process for the preparation of a clear solution is disclosed, including:

(a) mixing one part of the insoluble component to be dissolved with ten parts of emulsifier, possibly under gentle warming, in order to obtain a clear solution.

(b) mixing the above solution slowly with water, balance to 100 parts.

These measures correspond to the first and second step of the claimed process.

No dissolving aids are necessary and the portion of the water-insoluble component can be increased as long as the solution remains clear.

The fact that no mixing temperature is indicated for step (b) implies that the clear solution obtained in step (a) is then mixed with water in a temperature range around room temperature.

Samples No. 414E (orange oil solution) and 418E (lime oil solution) represent optically clear vitamin formulations for which the ratio of the ingredients is in the claimed range.

From the above disclosure in D2 the skilled person draws the following conclusions as regards the preparation of an optically clear solution:

- water insoluble (fat soluble) compositions, like oily vitamin compositions, can be mixed with certain hydrophilic emulsifiers in a ratio $\geq 1 : 10$ in order to obtain a clear solution;
- the solution can then be mixed with water at moderate temperatures to 100 parts in order to obtain a clear aqueous solution.

Document D2 therefore qualifies as a starting point for the assessment of inventive step of the claimed subject-matter.

2.3 Inventive step of the process according to the claims as granted (main request)

The subject-matter according to Claim 1 differs from the disclosure in D2 essentially in that a fat soluble vitamin compound is used instead of a vitamin dissolved in a vegetable oil and that a slightly higher mixing temperature is applied when adding water in the second step.

Therefore, the problem to be solved is seen in adapting the process conditions applied in D2 for vitamin oils to the preparation of an optically clear formulation containing a water insoluble vitamin component. The issue of the separation of the preparation conditions into two steps addressed in Table 1 of the patent specification is thus not reflected by the problem formulation, since the two-step technique is already realised in D2.

As concerns the different compositional status of the fat soluble vitamin (by itself or in oil solution), this difference is not considered by the Board to be decisive for the desired clarity of the solution, because in both cases an equivalent oil-in-water system is established. Nor has this issue been the subject of any argument from the Appellant/Patentee.

As to the mixing temperature, its choice is within the bounds of routine experimentation of a skilled person

seeking to adapt/optimize the process conditions for a certain vitamin/emulsifier combination with water. Raising this temperature from about room temperature to the range of 30 to 35°C does not therefore require an inventive effort.

It is moreover noted in this context that the only vitamin for which experimental evidence exists is vitamin E acetate oil.

Hence, the process of Claim 1 as granted does not involve an inventive step.

The main request is therefore not allowable.

2.4 Inventive step of the process according to the auxiliary request over document D2

The process according to Claim 1 of the auxiliary request requires that the emulsifier is polyoxyethylene(20)sorbitan mono-oleate, i.e. polysorbate 80/Tween80. In this conjunction the Appellant argues that the skilled person would not be motivated by the prior art to select polysorbate 80 from the vast number of possible emulsifiers in order to obtain the superior results of reduced turbidity of beverages as shown in the test report submitted with the Statement of Grounds of Appeal.

The Board does not accept this argument.

In particular, the Board adopts the position of the Respondent (see point VIII), that the comparative solutions of the test report containing the emulsifiers Tween 60 or fatty acid sucrose ester could not

initially have been optically clear because, according to the disclosure at page 16 of D2, optically clear solutions should remain clear after dilution with water: "A solution prepared in this way [ie being clear] can be further at will diluted with water". The test report does not therefore qualify as a means for establishing any special benefit of the selection of Tween 80 as an emulsifier.

Therefore, the problem to be solved by the subject-matter of Claim 1 of the auxiliary request vis-à-vis D2 is seen in providing a process for preparing an analogous optically clear vitamin solution by using a food-compatible emulsifier component.

Because the suitability of polysorbate 80/Tween 80 for food applications is known in the prior art (cf. paragraph [0012] of the patent specification), selection of this emulsifier and adaptation of the mixing parameters/conditions in accordance with the guidance given in the right-hand column at page 16 of D2 is an obvious option for a skilled person. This is all the more so as page 7 of D2 (right-hand column, lines 7-11) qualifies Tween 80 as one of two good solubilising agents for the preparation of O/W emulsions.

The subject-matter of Claim 1 of the auxiliary request is therefore also not inventive and the auxiliary request is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

D. Sauter

P. Kitzmantel