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**Datasheet for the decision
of 20 December 2016**

Case Number: T 0357/14 - 3.3.07

Application Number: 05020527.7

Publication Number: 1639989

IPC: A61K8/86, A61K8/33

Language of the proceedings: EN

Title of invention:

Microemulsion

Patent Proprietor:

KAO CORPORATION

Opponent:

L'Oréal

Headword:

Microemulsion/KAO CORPORATION

Relevant legal provisions:

EPC R. 99(2)

EPC Art. 54, 56, 123(2)

Keyword:

Admissibility of appeal - (yes)
Main request - Amendments (yes)
Main request - Novelty (yes)
Main request - Inventive step (yes)

Decisions cited:

Catchword:



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Case Number: T 0357/14 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 December 2016

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 December
2013 rejecting the opposition filed against
European patent No. 1639989 pursuant to Article
101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. European patent No. 1 639 989 (based on application No. 05 020 527.7) was granted on the basis of a set of 8 claims.

Independent claim 1 as granted read as follows:

"1. A microemulsion comprising the following ingredients (A) through (F):

(A) a hydrophilic nonionic surfactant having as a hydrophilic group a residue of a sugar, reducing sugar or polyglycerin having a hydrogen atom of at least one hydroxyl group thereof removed;

(B) a hydrophilic nonionic surfactant having a polyoxyethylene chain as a hydrophilic group;

(C) a water-soluble organic solvent selected from the group consisting of (C1) through (C3) listed below;

(C1) a compound having in a molecule thereof two or more oxypropylene groups (PO) and hydroxyl groups (OH) the ratio in number of said two groups (PO/OH) being smaller than 5;

(C2) a monohydric alcohol having a carbon number ranging from 2 to 6; and

(C3) a dihydric alcohol having a carbon number ranging from 2 to 6;

(D) a lipophilic nonionic surfactant selected from the group consisting of polyoxyethylene difatty acid esters, polyoxyethylene dialkyl ethers, monoglycerin monofatty acid esters, monoglycerin difatty acid esters, diglycerin monofatty acid esters, monoglyceryl monoalkyl ethers, diglyceryl monoalkyl ethers and sorbitan fatty acid esters, wherein the monoglycerin monofatty acid esters are selected from monoglycerin 2-ethylhexanoate ester, monoglycerin laurate ester,

monoglycerin myristate ester, monoglycerin palmitate ester and monoglycerin oleate ester,
(E) an oily ingredient; and
(F) water."

- II. An opposition was filed under Article 100 (a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed.
- III. The appeal by the opponent lies from the decision of the opposition division to reject the opposition. The decision was based on the claims as granted as main request.
- IV. The documents cited during the opposition proceedings included the following:
D1: WO0061083
D2: Complement Activation by Cremophor EL as a Possible Contributor to Hypersensitivity to Paclitaxel: an in Vitro Study - Oxford Journals Medicine JNCI, J. Nat. Cancer Inst., Vol. 90, Issue 4, , pp 300 (1998)
D3: WO96/28131
D4: DE19710155
D5: US5575990
D6: WO2005004835
D10: Test Report filed by the proprietor on 20.09.2013
- V. According to the decision under appeal, the subject-matter of claim 1 of the patent as granted was a combination of claims 1 and 7 of the application as originally filed and of the compounds D listed in paragraph [0046] of the description wherein two compounds had been deleted. The deletion of two members of a list and the replacement of a generic definition by a list of compounds could not add subject-matter,

and thus the subject-matter of claim 1 did not contravene the requirements of Article 123(2) EPC.

The priority of the patent was valid.

As regards novelty, examples 1-3 of D5 and example C and D of D6 disclosed microemulsions. Said examples did not comprise the claimed compound D. It was considered that POE(20) hydrogenated castor oil and PEG-40 hydrogenated castor oil disclosed in D1 and D6 did not represent a compound of the claimed D compound, in particular not a monoglycerin di-fatty acid ester.

As regards inventive step, D5 represented the closest prior art and disclosed in example V a microemulsion, comprising decyl polyglucose (compound A), octoxynol-6 (compound B), butylene glycol (compound C), cyclomethicone and isopropyl myristate (compounds E), and water (compound F). The compound PEG-7 glycerol cocoate present in example V could not be regarded as being an alternative monoglycerin mono-fatty acid ester falling under the definition of compound D. The claimed subject-matter differed thus from example V in the addition of a compound as defined as compound D. The objective technical problem was seen as the provision of a microemulsion that is stable over a wide range of temperature. This effect was shown by comparative example 4 of the patent and document D10, which though not showing a direct comparison with example V of D5, presented a similar composition without a compound of the category D. Neither D5, nor any other document gave any indication that particular types of non-ionic surfactants would lead to stability of microemulsions over a wide range of temperature. The subject-matter of claim 1 involved an inventive step over D5.

- VI. The opponent (hereafter called appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal the appellant submitted the following pieces of evidence:
D12: Fiche CTFA Cremophor EL
D13: Untersuchungen über Cremophor EL, Tenside, Februar 1996
- VII. With its reply to the statement of grounds of appeal dated 4 September 2014, the patentee (hereafter called respondent) contested the admissibility of the appeal by the opponent, filed auxiliary requests 1-9 and submitted a new document:
D14: Handbook of Cosmetic and Personal Care Additives
- VIII. A communication from the Board, dated 28 October 2016, was sent to the parties.
- IX. With a letter dated 28 November 2016, the respondent submitted new arguments on inventive step, auxiliary requests 10 and 11, and a new document:
D15: "Introduction to Macro- and Microemulsion", M.K. Sharma et al, ACS Symposium Series, 1985, pages 1-18.
- X. With a letter dated 12 December 2016, the appellant contested the respondent's arguments on inventive step filed with the letter dated 28 November 2016 and informed the Board and the respondent of its absence at oral proceedings.
- XI. Oral proceedings took place on 20 December 2016.
- XII. The arguments of the appellant may be summarised as follows:

Amendments

In claim 1, five specific mono-glycerin mono-fatty acid esters had been selected as lipophilic non-ionic surfactants. This list was not disclosed as such in paragraph [0046] of the original application (EP 1 639 989 A1) description, which comprised seven specific mono-glycerin mono-fatty acid esters. The selection of five such specific esters constituted therefore a selection which was not disclosed in the original application.

Priority

In view of the selection of the specific mono-glycerin mono-fatty acid esters in claim 1 of the claims as granted, the priority was not valid any more.

Novelty

D1 disclosed in examples 1-3 a microemulsion comprising all components (A)-(F) as claimed, with in particular POE(20) hydrogenated castor oil as component (D). As shown by D2, POE(20) hydrogenated castor oil was a complex mixture comprising in particular mono-, di- and tri-esters of polyethoxylated glycerol. D1 was therefore relevant for the novelty of at least claim 1 as granted.

D6 disclosed in examples C and D a microemulsion comprising components (A)-(C), (E) and (F), and PEG-40 hydrogenated castor oil as component (D). Claim 1 as granted lacked therefore novelty.

Inventive step

Document D5 was considered as closest prior art for the assessment of inventive step. Example V of D5 disclosed a microemulsion comprising components (A)-(C), (E) and (F). Example V also comprised PEG-7 glyceryl cocoate which was a non-ionic surfactant. The claimed subject-matter differed by the choice of a lipophilic non-ionic surfactant (D) chosen among the claimed list. The problem appeared to be the provision of a microemulsion stable over time and over a wide range of temperature. However, no effect had been demonstrated and no direct comparison had been made with the composition of example V of D5. The tests D10 showed a comparison between an example of the contested patent towards a composition comprising no (D) surfactant. The results of D10 or of the examples of the contested patent could also not be extrapolated to the whole claimed subject-matter, since they related only to specific surfactants. Consequently, the problem was the provision of an alternative composition. The solution was obvious, since the lipophilic non-ionic surfactants were known as components of microemulsions, as shown by example 6 of D3 and Table I of D4. There was thus a lack of inventive step over D5.

XIII. The arguments of the respondent may be summarised as follows:

Admissibility of the appeal

The statement setting out the grounds of appeal merely repeated the appellant's arguments from the first instance without supplying any substantive argument directed to the reasons for the decision under appeal. Accordingly, the requirements of Article 108 EPC, Rule 99(2) EPC, and Article 12(2) RPBA had not been met.

Amendments

Support for the list of the (D) components could be found in the last sentence of paragraph [0046] of the original application where a list of preferred monoglycerin monofatty acid esters is disclosed. The only difference between the list in paragraph [0046] and that appearing in claim 1 was that two of the monoglycerin monofatty acid esters (monoglycerin isostearate ester; monoglycerin stearate ester) were not included. The deletion of two members of a list and the replacement of a generic definition by a list of specific compounds could not add subject-matter beyond that derivable to the skilled person from the application as filed.

Novelty

The Opponent's novelty argument was based on two assumptions: (1) the term monoglycerin difatty acid esters in the definition of ingredient (D) had to be construed broadly to cover polyoxyethylenated monoglycerin difatty acid esters; and (2) the ingredient POE(20) hydrogenated castor oil in Examples 1-3 of D1 and the ingredient "PEG(40) hydrogenated castor oil in Examples C and D of D6 inevitably included such a polyoxyethylenated monoglycerin difatty acid ester. Both assumptions were wrong, and documents D1 and D6 were not relevant for novelty, since they do not disclose compositions with the component (D).

Inventive step

Example V of D5 had to be considered as closest prior art. The composition of example V included PEG-7 glyceryl cocoate, an hydrophilic non-ionic surfactant,

instead of the claimed component (D) which was a lipophilic non-ionic surfactant. The distinguishing feature was therefore the presence of component (D) in the claimed compositions. An attributable effect was shown in the examples of the patent and in the comparative tests D10.

Table 3 included a number of comparative examples where the ingredients as defined in claim 1 were either omitted (Comparative Examples 1-4) or replaced (Comparative Examples 5 and 6). Comparative Example 4 omitted ingredient (D), successively. It could be seen from the stability results for Comparative Example 4 that the omission of ingredient (D) led to a microemulsion composition that was not stable at any temperature between 5°C and 45°C. On the contrary, the microemulsion for each and every one of Examples 1-16 containing ingredient (D) was stable over this wide temperature range.

D10 provided data for three microemulsion compositions and their corresponding stabilities between 5°C and 45°C. The microemulsion of Example 11a corresponded to the microemulsion of Example 11 in Table 2 of the granted patent. Example 11b was also a microemulsion according to the claimed invention and differed from Example 11a in respect of the ingredient and amount used for ingredient (D): the ether "isostearyl glyceryl ether" has been replaced with the "ester diglycerol monoisostearate". In both cases the microemulsion was stable between 5°C and 45°C. Comparative Example 11 corresponded to both Examples 11a and 11b but with one crucial difference: ingredient (D) had been omitted. This microemulsion was not stable at any temperature between 5°C and 45°C.

It was clear from the data in the patent, as well as the data in D10, that the presence of ingredient (D) led to a stable emulsion at varied temperatures.

In view of the effect that was attributable to the distinguishing feature, the objective technical problem to be solved could be formulated as the provision of a more stable microemulsion over a wide range of temperatures.

There was no teaching in D5 that ingredient (D) could be used to increase stability over a wide range of temperatures. There was also no teaching in D3 or D4 that ingredient (D) could be used to increase stability of a microemulsion over such a wide range of temperatures. Starting from Example V of D5 and looking to solve the objective technical problem, the skilled person could not have known that incorporating ingredient (D) would solve the technical problem. Thus, the claimed invention was based on an inventive step.

Even if, for argument's sake, the objective technical problem was formulated less ambitiously, the claimed invention was still based on an inventive step. The compositions of D5 did not comprise a lipophilic non-ionic surfactant, and D5 even taught away from using lipophilic non-ionic surfactants at column 7, lines 16-19 where it stated that "Other water-soluble non-ionic surfactants having an HLB of between about 13 to about 18 may easily be tested as to suitability within the compositions of the present invention". The skilled person would thus not have considered adding a lipophilic non-ionic surfactant. Moreover, PEG-7 glyceryl cocoate was essential in example V for obtaining a clear composition (see col. 9, l. 37-61).

As regards D5, Example V of D5 comprised nonoxynol and dipropylene glycol and these components were added for the purpose of providing high and low temperature stability, respectively (column 3, lines 3-13). However, D5 did not explain what is meant by high and low temperature stability. It was thus not clear from D5 what was meant by "high/low temperature stability".

XIV. Requests

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

The respondent requested that the appeal be rejected as inadmissible or be dismissed. Alternatively, he requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests 1 to 9 filed with letter of 4 September 2014, or auxiliary requests 10 or 11 filed with letter of 28 November 2016.

Reasons for the Decision

1. Admissibility of the appeal

According to Rule 99(2) EPC, the appellant has to specify the legal and factual reasons on which the case for setting aside the decision was based. The arguments have to be clearly and concisely presented to enable the Board and the other party to understand immediately why the decision was alleged to be incorrect.

An appeal by an opponent is admissible if the grounds of appeal contain at least one reason for setting aside the impugned decision, as required by Rule 99(2) EPC (see T 0682/11).

In the present case, the appellant submitted a complete argumentation as regards amendments, novelty and inventive step of the granted claims. The statement of grounds of appeal is a direct answer to the decision of the opposition division since the argumentation of novelty is now supported by the newly filed documents D12 and D13, and an argumentation on inventive step is provided which deals with D5 as closest prior art, which was subject of the appealed decision. Therefore, the appeal is admissible.

2. Main request

2.1 Amendments - Article 100(c) EPC

The subject-matter of claim 1 of the main request has been amended by the incorporation of the subject-matter of original claim 7 and the incorporation of a list of preferred monoglycerin monofatty acid esters found in paragraph [0046] of the description (see the publication EP 1 636 989 A1), wherein two members of the list of 7 preferred monoglycerin monofatty acid esters have been suppressed. As such suppression cannot be seen as a selection, the claimed subject-matter is directly and unambiguously derivable from the application as originally filed.

2.2 Article 54 EPC - Novelty

D1 and D6 have been cited as documents relevant for novelty.

- 2.2.1 The subject-matter of claim 1 of the main request differs from the priority document by the amendment discussed under point 2.1 above, namely a selection of 5 preferred monoglycerin monofatty acid esters from a list of 7 (see par. [0046] of priority document JP2004274971). Since this amendment is directly and unambiguously derivable from the priority document, the priority of the contested patent remains valid.
- 2.2.2 D1 discloses microemulsions in examples 1-3, comprising all components A, B, C, E, and F as claimed and comprising additionally POE(20) hydrogenated castor oil.

According to the appellant, said POE(20) hydrogenated castor falls under the "monoglycerin di-fatty acid esters" claimed as compound D in claim 1 of the main request.

The Board could however not follow the appellant's argumentation, since it contravenes the normal interpretation and understanding of the chemical nomenclature. The term "monoglycerin difatty acid ester" used in claim 1 of the main request can in no way be understood as encompassing also its POE derivatives. The same applies to the term "monoglycerin monofatty acid esters" in claim 1.

Moreover, it is clear from the disclosure of documents D12 and D2 that POE derivatives of castor oil do not comprise di-fatty acid glycerides as residues of the preparation of such POE derivatives. Consequently, said POE(20) hydrogenated castor disclosed in D1 is not a "monoglycerin fatty acid ester", does not comprise any residue of "monoglycerin fatty acid ester", and

examples 1-3 do not disclose microemulsions comprising the compound D.

The claimed subject-matter is therefore new over D1.

- 2.2.3 D6 has been published after the filing date of the contested patent and is a document cited under Article 54(3) EPC, since the priority of said contested patent is valid.

D6 discloses in examples C and D microemulsions with the claimed components A, B, C3, E and F and comprising further PEG-40 hydrogenated castor oil. Such PEG derivatives cannot be considered to be classified as a "monoglycerin difatty acid ester" or as a "monoglycerin monofatty acid esters" as claimed in claim 1.

Examples C and D of D6 do therefore not disclose microemulsions comprising the component D.

The claimed subject-matter is new over D6.

- 2.2.4 The main request meets the requirements of Article 54 EPC.

2.3 Article 56 EPC - Inventive step

- 2.3.1 The invention relates to microemulsions having a stability over a wider temperature range. This stability is obtained by a certain combination of three specific surfactants with specific water-soluble organic solvents.

- 2.3.2 D5 has been considered as the closest state of the art and discloses in example 5 a composition comprising inter alia:

- Decyl polyglucose (compound A)
- Octoxynol-16 (compound B)
- Poloxamer 217 (compound B)
- Butylene glycol (compound C2)
- Dipropylene glycol (compound C3)
- Cyclomethicone (compound E)
- Isopropyl myristate (compound E)
- Water (compound F).

D5 further mentions that the compounds nonoxynol and dipropylene glycol are added to the compositions for obtaining a stability at respectively high and low temperatures of the microemulsion (see D5, col. 3, lines 3-13).

The composition disclosed in example V of D5 does thus not comprise a compound of the category D as claimed in claim 1 of the main request.

The Board could not follow the respondent's argumentation questioning the nature of the temperature stability achieved by the compositions disclosed in D5, since it appears clear from the teaching of D5 that it related indeed to the temperature stability of the microemulsions.

Moreover, the respondent challenged the reality of the microemulsion state of the compositions of D5, and considered that a further difference resided in the nature of the microemulsion system itself. In the Board's view, it is clear that the statements in the description of D5 relating to the size of the microemulsions and mentioning a possible size over 1 μm cast indeed serious doubts on the reality of said microemulsions disclosed in D5. The Board will however

start from the premises that D5 does disclose classical microemulsions with a submicron size.

- 2.3.3 According to the respondent, the problem is the provision of a microemulsion with improved stability over a wide range of temperatures.

The appellant considers that the problem is the provision of an alternative microemulsion stable over a wide range of temperatures.

- 2.3.4 As a solution to the alleged problem(s), claim 1 of the main request proposes a microemulsion comprising in particular a lipophilic nonionic surfactant (D) selected from the group consisting of polyoxyethylene difatty acid esters, polyoxyethylene dialkyl ethers, monoglycerin monofatty acid esters, monoglycerin difatty acid esters, diglycerinmonofatty acid esters, monoglyceryl monoalkyl ethers, diglycerly monoalkyl ethers and sorbitan fatty acid esters.

- 2.3.5 The respondent relies on comparative example 4 of the contested patent and on D10 to demonstrate said alleged effect of improved stability.

Example 4 of the contested patent discloses the following given comparative composition, which does not comprise any D compound:

- Polyglyceryl(5) monostearate ester (compound A)
- POE(12) laurate ester and POE(20) sorbitan laurate (compounds B)
- PPG(9) diglyceryl ether and PPG(10), PPG(24) diglyceryl ether (compounds C)
- Hydrogenated polyisobutene (compound E)
- Water (compound F)

Example 4 shows that this composition is unstable at any temperature between 5°C and 45°C.

D10 discloses the following comparative composition 11 which does not comprise any D compound:

- Polyglyceryl(5) monostearate ester (compound A)
- POE(12) laurate ester (compound B)
- Ethanol (compound C)
- Hydrogenated polyisobutene (compound E)
- Water (compound F) a comparison

It shows that such composition is also unstable at any temperature between 5°C and 45°C.

None of the compositions disclosed in the comparative examples of the contested patent or in D10 correspond however to the composition disclosed in example V of D5. Moreover, the compositions disclosed in D5 are explicitly mentioned to be stable at high and low temperature, and there is no reason to question this stability and also no evidence to the contrary shown in the contested patent or in D10. There is thus no evidence that a composition as claimed in claim 1 of the main request provides a better stability than the composition disclosed in D5.

Consequently, as stated by the appellant, the problem is the provision of an alternative microemulsion stable over a wide range of temperatures.

In view of the information found in the examples of the contested patent, the board is convinced that the problem has been plausibly solved.

- 2.3.6 It remains to determine whether the solution to this problem is obvious or not.

The oil-in-water emulsifying system disclosed in D5 comprises the following combination of components:

- (i) 0.5-3.0 wt. % Poloxamer 217,
- (ii) 0.5-3.0 wt. % glycereth-7-benzoate, and
- (iii) 0-5 wt. % of a nonionic surfactant for high temperature stability, e.g., a water soluble nonoxynol or an octoxynol (see D5, col. 2, l. 25-col.3, l. 17; col. 4, l. 3-42). In example V of D5 said emulsifying system specifically comprises 0.5% by weight of poloxamer 217, 0.5% by weight of glycereth-7-benzoate, and 3.00% by weight of octoxynol-16 as components (i)-(iii). D5 teaches that other water-soluble non-ionic surfactants could be added to the disclosed compositions, but mentioned that said surfactant needed to have an HLB comprised between 13 to 18, thus very hydrophilic surfactants (see D5, col. 7, lines 9-26). There is no further teaching in D5 that a supplementary lipophilic non-ionic surfactant can be added in said emulsifying system.

The Board could also not follow the appellant's argumentation that the compound PEG-7 glycerol cocoate present in example V of D5 could be regarded as being an alternative monoglycerin mono-fatty acid ester falling under the definition of compound D. The structure is indeed different in view of the presence of the polyoxyethylene groups in PEG-7 glycerol cocoate. The presence of said POE hydrophilic groups makes the arguments of the respondent, namely that PEG-7 glycerol cocoate has a high HLB and is rather hydrophilic, even more credible.

Moreover, it is commonly known that microemulsions are complex structures, for which there is no reliable predictive method for selecting the emulsifier,

emulsifying system or technique of emulsification for obtaining said microemulsion structure (see for instance, D15, pages 11-12). There is therefore no certainty that the addition of a lipophilic non-ionic surfactant (D) selected from the specific group of claim 1 of the main request to the emulsifying system disclosed in D5 would lead to the formation of a microemulsion, even less a stable microemulsion.

Finally, it is true that the use of a lipophilic non-ionic surfactant such as a diglycerin monofatty acid ester or a monoglycerin monofatty acid ester such as glycerin-monooleate in microemulsions was known from documents D3 and D4 (see D3, example 6 or D4, Table 1), but said surfactants are integrated in an emulsifying system different from the emulsifying system used in example V of D5, or the emulsifying system of the present invention. A transposition of the emulsifying system as disclosed in D3 or D4 to the system of example V of D5 is thus possible.

The solution according to the subject-matter of claim 1 is therefore not obvious. The same applies to claims 2-8 which all refer directly or indirectly to claim 1.

- 2.3.7 The main request meets the requirements of Article 56 EPC.

- 2.3.8 As this was the only line of argumentation on inventive step put forward by the appellant, which as it appears from above failed, the decision of the opposition division holds good and remains valid.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



Decision electronically authenticated