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D E C I S I O N
of 13 July 2005

Case Number: T 0680/00 - 3.3.7

Application Number: 92307400.9

Publication Number: 0529883

IPC: A61K 7/00

Language of the proceedings: EN

Title of invention:
Microemulsion

Patentee:
UNILEVER PLC and UNILEVER N.V.

Opponent:
KPSS-Kao Professional Salon Services GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54, 83

Keyword:
"Sufficiency of disclosure (yes)"
"Novelty (no)"
"Auxiliary requests: properties specified in the claims inherent to the known compositions"

Decisions cited:
-

Catchword:
-

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Case Number: T 0680/00 - 3.3.7

D E C I S I O N
of the Technical Board of Appeal 3.3.7
of 13 July 2005

Appellant: (Proprietor of the patent)
UNILEVER PLC
Unilever House
Blackfriars
London EC4P 4BQ (GB)

UNILEVER N.V.
Weena 455
NL-3013 AL Rotterdam (NL)

Representative:
Mulder, Cornelis Willem Reinier, Dr.
Unilever PLC
Patent Division
Colworth House
Sharnbrook,
Bedford MK44 1LQ (GB)

Respondent: (Opponent)
KPSS-Kao Professional Salon Services GmbH
Pfungstädterstrasse 92-100
D-64297 Darmstadt (DE)

Representative:
-

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 26 May 2000 revoking European patent No. 0529883 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: R. E. Teschemacher
Members: P. A. Gryczka
B. J. M. Struif

Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 529 883 in respect of European patent application No. 92 307 400.9, filed on 12 August 1992 and claiming the priority date of 16 August 1991 from GB 91 17 740, was published on 22 January 1997.

II. A notice of opposition was received on 20 October 1997 in which revocation of the patent was requested on the grounds of insufficiency of disclosure and lack of novelty and inventive step (Article 100(a) and (b) EPC).

The following documents were cited, *inter alia,* during the opposition proceedings:

D1: EP-A-0 268 982

D2: EP-A-0 432 951

D4: EP-A-0 138 192

D6: EP-A-0 228 575

D7: EP-A-0 226 337

D8: M. Bourrel et al., Microemulsions and Related Systems: Formulation, Solvency and Physical Properties, Marcel Dekker, Inc., New York and Basel, (1988), pages 25 to 27.

III. In a decision issued in writing on 26 May 2000, the opposition division revoked the patent. The decision was based on an amended set of claims 1 to 10 filed as sole request on 28 May 1998. Claim 1 of said request read as follows:

"1. A shampoo composition comprising:
(a) microemulsified particles of a conditioning oil having a particle size of ≤ 0.15 microns;
(b) a deposition polymer; and
(c) in addition to the microemulsified conditioning oil itself, from about 0.1 to about 50% by weight of at least one surfactant; wherein the deposition polymer is a cationic derivative of guar gum or a cationic cellulose ether derivative."

In its decision the opposition division held that:

(a) The amended claims met the requirements of Article 123(2) and (3) EPC. The claims were not rendered unclear by the amendments.

(b) Microemulsions were known in the art before the priority date of the contested patent. The fact that it was difficult to make a distinction between microemulsions, emulsions and micellar solutions was not an evidence that the invention was insufficiently disclosed. There might be an overlap between the particle size ranges of these different types of solutions, however, the patent clearly defined that the particle size should not exceed 0.15 microns. Thus, the invention was sufficiently disclosed in the opposed patent (Article 83 EPC).

(c) Document D2 disclosed a shampoo composition comprising microemulsified particles of a conditioning oil silicone having a particle size of preferably 0.01 to 1 micron, a deposition

polymer which was a cationic derivative of guar gum and from 5 to 30% by weight of a surfactant. This general disclosure of the particle size had to be taken into account for the assessment of novelty. The fact that the examples of D2 did not mention the claimed particle size was irrelevant, since D2 unambiguously disclosed a particle size of 0.01 micron. D2 did not directly mention microemulsions. However, emulsions having a particle size of 0.01 micron must inevitably be microemulsions. In fact, D8 stated that macroemulsions had particle sizes above 0.1 microns whereas according to D4 microemulsions had a particle size of less than 0.14 microns. It was irrelevant whether emulsions with such small particles were named microemulsions or micellar solutions since both had, according to D8, identical characteristics, such as thermodynamic stability. There was no evidence of the existence of thermodynamically unstable macroemulsions having particles sizes corresponding to microemulsions. The specific disclosure in D2 of particle sizes of 0.01 microns, which was less than one tenth of the upper limit of the particle size in the opposed patent, could thus only be interpreted as referring to microemulsions. Therefore, the subject-matter of claim 1 was not novel (Article 54 EPC).

IV. The Proprietor (Appellant) lodged an appeal against the above decision, received on 4 July 2000, the appeal fee being paid on the same day. With the statement setting out the grounds of appeal, received on 5 October 2000,

the Appellant filed two sets of amended claims as first and second auxiliary requests.

Claim 1 of the first auxiliary request differed from claim 1 of the main request in that at the end thereof the following feature is added:

"and wherein the shampoo composition is optically clear or translucent".

Claim 1 of the second auxiliary request differed from claim 1 of the main request in that at the end thereof the following feature is added:

"and wherein the shampoo composition is mechanically stable".

V. In a letter dated 9 January 2001, the Respondent (Opponent) filed the following document:

D11: B.W. Müller and P. Kleinebudde , "Untersuchungen an sogenannten Mikroemulsionssystemen", Pharm. Ind., 50(3), 1988, pages 370 to 375.

VI. Oral proceedings took place on 13 July 2005.

VII. The Appellant's arguments can be summarised as follows:

(a) The conclusion of the Opposition Division that emulsions with a particle size of 0.01 micron, as disclosed in D2, must inevitably be microemulsions was not correct. As shown by document D8, the droplets size was not necessarily the critical factor in determining whether or not an emulsion

was a microemulsion. In fact, the critical factor was that a microemulsion was thermodynamically stable, i.e. that the emulsified particles remained emulsified despite the action of an external force on the emulsion. The compositions disclosed in D2 were prepared by mechanically mixing the silicone and water. This method could not lead to microemulsions, which had to be prepared by specific methods, in particular by the method disclosed in D4 and D6. In addition, the compositions in accordance with the examples of D2 included a stability enhancing agent, thus indicating that they would be thermodynamically unstable in absence of such agent. Furthermore, it was well known that microemulsions were distinguished from emulsions by their transparency. In accordance with D2 the silicone was insoluble in the aqueous matrix and was present as dispersed particles, which clearly was not consistent with a single stable phase required for microemulsions. Hence, the subject matter of claim 1 and of the subsequent claims of the main request was novel (Article 54 EPC).

(b) In the claims of the first auxiliary request, the compositions were further characterized in that they had to be optically clear or translucent in contrast to the compositions of D2 which were opaque. Accordingly, the subject-matter of the claims of the first auxiliary request was novel (Article 54 EPC).

(c) In the claims of the second auxiliary request it was specified that the claimed composition had to

be mechanically stable. Also, this characteristic was not disclosed in D2. Accordingly, the subject-matter of the claims of the second auxiliary request was novel (Article 54 EPC).

VIII. The Respondent submitted that:

(a) In the present case, the issues of insufficiency of disclosure and novelty were linked. As evidenced by D8 and D11, no clear definition for the term microemulsion was generally recognized in the art at the priority date of the opposed patent. The requirement of thermodynamic stability introduced in the definition of microemulsions by the Appellant in order to establish novelty, was a further parameter which was not defined in the opposed patent. In particular, it was not indicated under which conditions a microemulsion should fulfil this requirement. Sufficiency could be acknowledged if the definition of microemulsions was restricted to a specific particle size. However, this had the consequence that novelty with regard to D2 had to be denied.

(b) The emulsions in accordance with D2 had a particle size from 0.01 to 1 micron, thus including to a major part particle sizes corresponding to microemulsions. The lower limit of this range unambiguously disclosed a particle size in accordance with claim 1 of the patent in suit. The alleged thermodynamic stability of the claimed compositions could not be a distinctive characteristic, since it was known from D8 that the thermodynamic stability of emulsions was

increasing with decreasing particle sizes. Thus, the composition disclosed in D2 with a particle size of 0.01 micron was inherently thermodynamically stable. Consequently, the subject matter according to the claims of the main request was not novel (Article 54 EPC).

(c) The claims of the first auxiliary request were not clear as the terms "optically clear" and "translucent" were not precisely defined (Article 84 EPC). In addition, a microemulsion with a particle size of 0.01 micron, as disclosed in D2, was inherently translucent or optically clear as this property was directly linked to the particle size of the microemulsion. Consequently, the subject-matter of the claims of the first auxiliary request was not novel (Article 54 EPC).

(d) The claims of the second auxiliary request were not clear either, as the expression "mechanically stable" was not defined, since the description of the opposed patent did not mention any parameter which had to be fulfilled in this respect (Article 84 EPC). Novelty could not be recognised on the basis of this feature which was also inherent to the microemulsions of D2 (Article 54 EPC).

IX. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims underlying the decision under appeal (main request), alternatively on the basis of one of the sets of claims submitted as first and

second auxiliary requests with the letter dated 5 October 2000.

The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Novelty*

2.1 Document D2 discloses an aqueous shampoo composition comprising, in addition to water, (a) from 2 to 40% by weight of surfactant chosen from anionic, nonionic, or amphoteric surfactants or mixtures thereof; (b) from 0.01 to 3% by weight of cationic conditioning polymer which is a cationic derivative of guar gum; (c) from 0.1 to 10% by weight of an insoluble, non-volatile silicone, present as emulsified particles with an average particle size of less than 2 microns, preferably from 0.01 to 1 micron (claims 1 and 8, page 4, lines 1 to 3).

2.2 The compositions of D2 contain, as the compositions in accordance with claim 1 of the patent in suit, a cationic derivative of a guar gum and a surfactant in an amount of from 2 to 40% by weight, said amount falling under the claimed amount of 0.1 to 50% by weight. The insoluble non-volatile silicone is described in D2 as a conditioning agent (page 2, lines 15 and 16). This conditioning agent is present as

a preformed emulsion having average particle sizes of preferably from 0.01 to 1 micron (page 4, lines 1 to 3, claim 8). This particle size range encompasses particle sizes of ≤ 0.15 micron required by claim 1 of the patent in suit. In particular, the lowest limit of the particle size range, i.e. 0.01 micron represents an unambiguous disclosure of a particle size envisaged by claim 1 in suit. According to the Appellant, the particles were defined in D2 as being "***emulsified***", whereas claim 1 of the opposed patent required that they were "***microemulsified***" (emphasis added by the Board), which differentiated the claimed compositions from those of D2. Thus, the question arises whether the terminology "microemulsified" implies technical features which could distinguish the claimed compositions from those disclosed in document D2. For this purpose the meaning of technical terms used in connection with microemulsions must be determined.

2.2.1 The description of the opposed patent refers to the expressions "microemulsified" as well as to the expression "emulsified" when describing the invention (page 2, lines 4 and 59). Both terms are supplemented by the information that the particle size is ≤ 0.15 micron (page 2, line 33 and 59). Thus, no distinction is made between "emulsified" and "microemulsified" which are both used to describe particles in accordance with the invention.

2.2.2 Various prior art documents cited in the course of the proceedings relate to emulsions and microemulsions. In accordance with D6 microemulsion droplet sizes are variously defined with an upper limit of the droplet size typically being placed somewhere between 0.10 and

0.15 micron to distinguish microemulsions from opaque standard emulsions (page 4, lines 32 to 34). D6 makes also a direct link between the droplet size and the fact that microemulsions are transparent or translucent, specifying that microemulsions display greater clarity and stability when the particle size is decreased to less than 0.10 micron (page 4, lines 32 to 38). According to D7, microemulsions have an average droplet size in the range of about 0.001 to about 0.2 micron in diameter (page 3, lines 4 to 11; claim 1). D1 exemplifies a stable, transparent composition named **microemulsion** (emphasis added by the Board) with an average particle size of 0.05 micron (example 1, page 4, lines 55 and 56) and for comparative purposes an unstable turbid **emulsion** (emphasis added by the Board) with an average particle size of 0.8 micron (comparative example 1, page 5, lines 19 and 20). D4 discloses oil-in-water polyorganosiloxane emulsions and mentions that the emulsions obtained from transparent and clear oil concentrate having an average particle size of 0.14 micron are generally referred as "microemulsions" (page 7, lines 4 to 11; claim 10). Document D8 mentions that the drops of emulsions are generally large, i.e. larger than 0.1 micron, so that emulsions often take on a milky rather than the transparent and or translucent appearance of micellar solutions (page 26, second paragraph). Thus, D8 makes a direct link between the particle size and the appearance of the emulsion. D8 also mentions that the drop size is not the critical factor and that emulsions are distinguished from microemulsions by the fact that the average drop size grows continuously with time, so that emulsions will ultimately separate into two distinct phases (page 26, second paragraph). The

meaning of the first statement remains rather vague, since it is not said for which purpose the drop size is not considered critical. Thus, it cannot be derived from this passage that the instability is not linked to the particle size and that when the particle size is as low as to provide something generally referred as microemulsion, the separation of phase still occurs.

2.2.3 In summary, various prior art documents confirm that the terminology "microemulsion" or "microemulsified" merely describes emulsions with a given particle size and showing properties, i.e. transparency and stability, directly linked to that particle size. No other physical features are described which could unambiguously be linked to the terminology "microemulsified". The Appellant has not contested that characteristics such as thermodynamic stability and transparency are directly linked to the particle size of the droplets. In other words, when an emulsion is characterised by small droplet sizes as defined in the present claim, the thermodynamic stability and transparency are direct consequences of said droplet sizes.

2.2.4 In addition, it is not contested that no precise definition was recognised in the art for microemulsions. This is confirmed, for example, by document D11 which specifically mentions that the definitions of microemulsions in the literature are even contradictory (Summary; paragraph 2.1). In accordance with document D8, attempts to distinguish between micellar solutions and microemulsions introduce into the definition a degree of arbitrariness which makes a distinction rather artificial (page 26, last paragraph). As no

clear definition for microemulsions was generally accepted in the art and as the patent itself gives no definition in this respect (point 2.3), no precise characteristics generally recognised in the art can be linked to the fact that an emulsion is defined as a "microemulsion".

2.2.5 Consequently, the terminology "microemulsified" in the patent in suit does not imply technical characteristics, in addition to the particle size and the properties inherent to it, which can distinguish the claimed shampoo compositions from that disclosed in document D2.

2.3 Thus, the emulsion with an average particle size of 0.01 micron disclosed in D2 can be considered as a microemulsion in the context of the opposed patent and the mere fact that it is named "emulsion" and not "microemulsion" has no implications on novelty.

2.4 The Appellant argued that D2 was not an enabling disclosure, since the process of preparation of the emulsion disclosed in D2 could not provide microemulsions with particle sizes of less than 0.15 micron. The Board cannot share this opinion for the following reasons.

2.4.1 In accordance with D2, the silicone materials are preferably incorporated in the shampoo composition as a pre-formed aqueous emulsion, where the particle size of the silicone material in the emulsion is preferably from 0.01 to 1 micron. The emulsions may be prepared by high shear mixing of the silicone and water, or by emulsifying the insoluble, non-volatile silicone with water and an emulsifier, mixing the silicone into a

heated solution of an emulsifier or, by a combination of mechanical and chemical emulsification (page 4, lines 1 to 8). Thus, D2 mentions various possibilities for preparing the emulsions with different particle sizes from 0.01 to 1 micron. It might be true that a simple high shear mixing cannot provide particle sizes of less than 0.15 micron. However, D2 mentions also a process involving chemical emulsification for which the Appellant did not argue that it does not provide the required low size particles.

2.4.2 In addition, the patent application itself mentions that various methods of making microemulsions of particles of conditioning oils were available and well known and documented in the art (page 2, lines 48 and 49). More particularly, the patent in suit refers to the methods disclosed in documents D4 and D6 (page 2, lines 51 to 57). D4 and D6 were published respectively in 1985 and 1987, before the disclosure of the emulsions by document D2 (1991). D4 discloses a process for preparing microemulsions with a particle size of 0.14 micron or less (claims 1 and 2), whereas D6 discloses a method for obtaining microemulsions with particle sizes of less than 0.15 micron (claims 1 and 2). In fact, the particle sizes obtained by the method of D4 were as low as 0.048 micron (example 4, page 26, runs 5 and 6) and those obtained in D6 as low as 0.026 micron (page 11, table 6, example 9b). Whereas the method of D4 essentially involves mixing the ingredients in the presence of an emulsifier, the method of D6 is based on an *in situ* polymerization. Consequently, mechanical and chemical methods for preparing microemulsions with particle sizes below 0.15 micron were known to the skilled person before the

publication of document D2 and could be used to prepare emulsions having a particle size of 0.01 micron. Thus, in the absence of any evidence to the contrary, the disclosure by document D2 of emulsions having an average particle size of 0.01 micron is considered as an enabling disclosure.

2.5 Consequently, the emulsified particles with a particle size of 0.01 microns disclosed in D2 fall under the definition "microemulsified particles having a size of ≤ 0.15 micron" of claim 1 of the opposed patent. As the shampoo compositions of D2 include also all the other ingredients defined in claim 1 of the opposed patent (point 2.2), the claimed subject matter lacks novelty (Article 54 EPC).

First auxiliary request

3. When compared to the main request, the subject matter of claim 1 of the first auxiliary request is further defined by the feature *"and wherein the shampoo composition is optically clear or translucent"*. As the optical clarity or translucency is a direct consequence of the particle size of the microemulsion (point 2.2.3), the microemulsions with a particle size of 0.01 microns disclosed in D2, inherently are clear or translucent. D2 mentions the possibility of adding, among other ingredients, a pearlescer to the compositions (page 4, lines 45 to 49). Although this agent may interfere with the transparency of the emulsion, its addition is optional and is not mentioned in the claims of D2 which form the basis of the novelty destroying disclosure.

Consequently, the subject matter of claim 1 of the first auxiliary request lacks novelty for the same reasons as the main request (point 2).

Second auxiliary request

4. When compared to the main request, the subject matter of claim 1 of the second auxiliary request is further defined by the feature *"and wherein the shampoo composition is mechanically stable"*.

The patent in suit does not specify the requirement "mechanically stable". It is even doubtful whether the addition of this feature does not render the claim unclear (Article 84 EPC). In any case, as the patent does not mention any additional technical feature which should be observed in order to achieve mechanical stability, it must be concluded that the mechanical stability is an inherent property of the shampoo compositions fulfilling all physical and chemical characteristics set out in claim 1. Consequently, the specification in claim 1 that the shampoo composition is "mechanically stable" does not add any distinction which could render the claimed compositions novel over D2.

Therefore, the subject matter of claim 1 of the second auxiliary request lacks novelty for the same reasons as set out for claim 1 of the main request (point 2).

Sufficiency of disclosure

5. As submitted by the Respondent, the questions of novelty and sufficiency of disclosure are linked in the

present case. For the assessment of novelty the Board has come to the conclusion that the thermodynamic stability of the claimed compositions is an inherent property linked to the particle size (point 2.2.3). *Mutatis mutandis* the Board concludes that no additional measures beside those indicated in the patent in suit have to be observed when preparing the claimed compositions. Consequently, the Board is satisfied that the invention is sufficiently disclosed for it to be carried out be the skilled person, so that the requirements of Article 83 EPC are met. However, as none of the requests fulfils the requirement of novelty, the issue of sufficiency of disclosure has no impact on the outcome of the appeal.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

U. Bultmann R. E. Teschemacher