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Datasheet for the decision of 16 July 2019

Case Number: T 2321/16 - 3.3.07

Application Number: 04815090.8

Publication Number: 1696866

IPC: A61K8/22, A61Q11/00, A61K8/19

Language of the proceedings: EN

Title of invention:
Emulsion composition for delivery of bleaching agents to teeth

Patent Proprietor:
The Procter & Gamble Company

Opponent:
Colgate-Palmolive Company

Headword:
Bleaching agents/ P&G

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 123(2), 54, 56

Keyword:
Late-filed evidence - submitted with the statement of grounds of appeal
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

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Case Number: T 2321/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 July 2019

Appellant: (Patent Proprietor)	The Procter & Gamble Company One Procter & Gamble Plaza Cincinnati, OH 45202 (US)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Respondent: (Opponent)	Colgate-Palmolive Company 300 Park Avenue New York NY 10022 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 August 2016 revoking European patent No. 1696866 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	S. Albrecht
Members:	A. Usuelli
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 1 696 866 was granted on the basis of 10 claims. Independent claim 1 read as follows:

"1. A bleaching composition, in the form of a water-in-oil emulsion, for whitening teeth comprising:
a) from 1% to 45%, by weight, of an aqueous phase;
b) a safe and effective amount of a bleaching agent;
c) at least 30%, by weight, of an inert, continuous, hydrophobic phase;
d) from 0.001% to 30%, by weight, of an emulsifier;
wherein the composition is an emulsion in which the inert hydrophobic phase is in predominant proportion relative to the aqueous phase."

The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed. The following documents were among those cited during the proceedings before the opposition division:

D1: WO 02/34221
D3: US 2003/0180229
D11: US 2003/0219389
D12: Introducing Pemulen Polymeric Emulsifiers, Technical data sheet, January 2002
D15: GanzPearl - Technical data sheet, copyright 2004.

II. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division to revoke the patent. The decision was based on the patent as granted as the main request and on five auxiliary requests filed on 26 February 2015 (auxiliary requests 1 to 4) and during the oral proceedings held on 23 June 2016 (auxiliary request 5).

The opposition division held that the composition for whitening teeth defined in claim 1 of the patent differed from the compositions of the closest prior art document D11 in that it was a water-in-oil emulsion. The experimental data disclosed in paragraph [0041] of the patent were no evidence that the distinguishing feature resulted in an improvement over the closest prior art. The technical problem was therefore the provision of an alternative tooth whitening composition. D1 suggested the possibility of using water-in-oil emulsions for the delivery of oral care actives, such as tooth whitening agents, in the oral cavities. Hence, the subject-matter of the patent was obvious over the combination of D11 and D1.

The subject-matter of the auxiliary requests did not comply with the requirements of Article 56 EPC substantially for the same reasons given in respect of the main request.

III. With the statement setting out the grounds of appeal filed on 5 December 2016, the appellant defended its case on the basis of the same requests submitted during the proceedings before the opposition division. With the same submission it filed *inter alia* the following documents:

D16: Experimental report in support of EP 1 696 866
D16a: Unsigned version of D16

IV. In its reply of 19 April 2017, the opponent (respondent) requested that documents D16/D16a not be admitted into the appeal proceedings.

V. In a communication pursuant to Article 15(1) RPBA issued on 15 May 2019 the Board, in relation to the assessment of inventive step, expressed the opinion that document D11 was the closest prior art. It further considered that the main point of discussion during the oral proceedings was whether the skilled person having regard to the teaching of D1 would have considered to provide the compositions of D11 in the form of water-in-silicone emulsions.

VI. With letter dated 3 July 2019 the appellant filed auxiliary requests 6 to 17 and submitted arguments on inventive step in relation to the teaching of documents D1 and D11.

VII. During the oral proceedings held on 16 July 2019 the respondent requested that the appellant's submissions of 3 July 2019 not be admitted into the proceedings.

VIII. The appellant's arguments can be summarised as follows:

(a) Admittance of documents D16/D16a

The experiment for determining the whitening index disclosed in D16/D16a was substantially the same experiment described in [0041] of the patent. It was filed in response to the decision of the opposition division to formulate the technical problem as the provision of an alternative composition. This was in contrast to the formulation of the technical problem made by the opposition division in its preliminary opinion. Accordingly, D16/D16a could not have been filed earlier.

(b) Admittance of the submissions made on 3 July 2019

The arguments presented in the letter of 3 July 2019 were based on an analysis of the content of documents D1 and D11. They were submitted in reply to the communication of the Board. There was no reason for not admitting them.

(c) Article 123(2) EPC

The amendments made to the application as filed which resulted in the granted patent complied with the requirements of Article 123(2) EPC for the reason given in the decision.

(d) Novelty

The composition of example 1 of D3 was not a water-in-oil emulsion. Hence, this document did not anticipate claim 1 of the patent.

(e) Inventive step

Document D11 was the closest prior art for the assessment of inventive step. The composition of claim 1 of the patent in suit differed from those of D11 in that it was a water-in-oil emulsion. As explained in the patent, this form promoted an increase of the bleaching agent's concentration in contact with the teeth. This resulted in an improvement of the whitening index. These effects were supported by the data disclosed in the patent and in D16/D16a. Document D1, relied upon by the respondent, related to oral compositions comprising a silicone derivative that could be formulated as a water-in-silicone emulsion. However, this document did not address the problem of

increasing the efficacy of the bleaching composition while maintaining a good tolerability as D11. Additionally, there was a technical incompatibility between the teachings of D1 and D11. Thus, the skilled person had no reason to combine these documents. Moreover, example 7 of D1, discussed by the respondent in its submissions, did not relate to a water-in-oil emulsion. The subject-matter of the patent was therefore inventive.

IX. The respondent's arguments can be summarised as follows:

(a) Admittance of documents D16/D16a

In its preliminary opinion, the opposition division had stated that there were no comparative data with the closest prior art. Hence, D16/D16a could and should have been filed in reaction to this opinion during the first instance proceedings. In any case D16/D16a were not *prima facie* relevant since the reference composition tested in the experiments was not a composition according to D11. Thus, D16/D16a were not to be admitted into the appeal proceedings.

(b) Admissibility of the submissions made on 3 July 2019

The letter of 3 July 2019 contained some assertions in relation to the properties of water-in-silicone emulsions which were presented as factual evidence. This letter should therefore not be admitted into the appeal proceedings since it amounted to the introduction of new evidence shortly before the date of oral proceedings.

(c) Article 123(2) EPC

The subject-matter of claim 1 of the patent could not be derived from the orignal application. In particular, the feature defining the amount of emulsifier was not disclosed in combination with a water-in-oil emulsion as recited in granted claim 1. Hence, the requirements of Article 123(2) EPC were not met.

(d) Novelty

Claim 1 as granted was not novel over the composition of example 1 of D3 which comprised a discontinuous phase A dispersed throughout the continuous phases B and C.

(e) Inventive step

Document D11 related to tooth whitening compositions characterised by a specific peroxide concentration and a specific peroxide density. These compositions could be provided in any form. Although D11 did not disclose water-in-oil emulsions, these were encompassed by the general teaching of this document. In the experimental report D16/D16a only one composition according to claim 1 of the patent was tested. The experiments of D16/D16a were no evidence of an improvement over the compositions of D11. The technical problem was therefore the provision of an alternative tooth whitening composition. D11 did not disclose any specific example. Thus, in order to implement the teaching of this document the skilled person had to provide a suitable composition. D1 disclosed silicone oral care compositions which could contain a bleaching agent and formed a substantive film on the surface of the teeth. At page 6, D1 indicated that water-in-

silicone emulsions further enhanced the dispersion of water soluble actives in the water phase. The teachings of D1 and D11 were not incompatible as maintained by the appellant. Thus, the skilled person seeking to provide a composition according to the teaching of D11 would have been motivated by D1 to prepare a water-in-silicone emulsion, which was a specific type of water-in-oil emulsion.

The patent was obvious also when considering the teaching of D1 alone. Example 7 of this document disclosed a water-in-silicone emulsion containing triclosan as oral care active. By replacing triclosan with a peroxide, an alternative oral care active, the skilled person would have arrived at the composition of claim 1 of the patent without any inventive effort.

X. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1-5, filed on 26 February 2015 (auxiliary requests 1-4) and during the oral proceedings on 23 June 2016 (auxiliary request 5), or on the basis of one of auxiliary requests 6-17 filed on 3 July 2019.

XI. The respondent requested that the appeal be dismissed, that documents D16/D16a not be admitted into the proceedings, that the appellant's submissions dated 3 July 2019 not be admitted into the proceedings and that auxiliary requests 6-17 not be admitted into the proceedings.

Reasons for the Decision

1. Admittance of documents D16 and D16a

1.1 The appellant filed the experimental report D16 (and its unsigned version D16a) with the statement setting out the grounds of appeal.

In the decision under appeal the opposition division considered that the experimental data reported in paragraph [0041] of the patent could not be used to establish a comparison over the closest prior art since no information was given as to the composition of the reference formulation B (point 16.7 of the decision).

1.2 The experiment for determining the whitening index disclosed in D16 is substantially the same experiment described in [0041] of the patent. However, D16 provides information as to the composition of the reference formulation B. Thus, the filing of the new experimental report is a direct response to the considerations made by the opposition division in its decision. As it addresses a central part of the opposition division's finding on inventive step it is also *prima facie* relevant.

1.3 In the respondent's view, D16 should have been submitted earlier since in the summons to oral proceedings the opposition division commented on the absence of comparative data over the closest prior art.

However, as remarked by the appellant, despite the remark on the absence of comparative data, the opposition division came nevertheless to the conclusion that the technical problem over the closest prior art was the provision of an improved tooth whitening

formulation. Thus, in the Board's view, it cannot be concluded that on the basis of the comments made by the opposition division in its summons the appellant should have filed D16 during the first instance proceedings (Article 12(4) RPBA).

1.4 Hence, the Board decides to admit documents D16/D16a into the appeal proceedings.

2. Admittance of the appellant's submissions of 3 July 2019

2.1 During the oral proceedings before the Board, the respondent argued that some assertions contained in the appellant's letter of 3 July 2019 were to be regarded as a late submission of new facts. It referred in particular to paragraph 44 according to which "*[f]or the water-in-silicone emulsion of D1, at high amounts of water (which is required to achieve the high concentrations in D11) in a water-in-silicone emulsion would result in large droplets. And large droplets have a tendency to coalesce*."

2.2 The Board notes that the statements contested by the respondent are not substantiated by any means of evidence, such as a reference to a general textbook. In the Board's view, these statements are mere assertions which do not qualify as facts. They rather form part of arguments based on an assessment of the content of D1 and D11. The extent to which the appellant's arguments contain mere assertions is a matter which the Board has to take into account when evaluating the arguments.

Having regard to the fact that in its preliminary opinion of 15 May 2019 the Board indicated that the requirement of inventive step was to be assessed mainly

on the basis of the combination of the teachings of D1 and D11, the Board sees no reason for not admitting the appellant's submissions of 3 July 2019.

Main request (patent as granted)

3. Article 123(2) EPC

3.1 In claim 1 of the patent the amounts of components c) and d) differ from the amounts recited in claim 1 of the original application.

3.1.1 The hydrophobic phase (component c)) is present in an amount of "at least 30%". According to claim 1 of the original application, component "c" was present in "a safe and effective amount, preferably from 30% to 99%...".

The Board notes that the range "30% to 99%" in original claim 1 is merely a preferred embodiment. In a more general embodiment component "c" can be present in "a safe and effective amount". The figure "99%" results in a total amount of components that (slightly) exceeds 100%. Thus, the deletion of the upper limit "99%" does not in the Board's view contravene Article 123(2) EPC since this upper limit is not a mandatory feature of original claim 1 and is clearly erroneous. The maximum amount of component "c" in original claim 1 is determined by the amounts of the other components. However, this requirement is implicitly incorporated also in claim 1 as granted.

Thus, the feature of claim 1 "at least 30%" does not contravene the requirements of Article 123(2) EPC.

3.1.2 In original claim 1 the emulsifier is present "in a safe and effective amount" whereas claim 1 of the patent requires an amount of 0.001 to 30%. The original description (page 11) indicates four specific ranges for the emulsifier, the first one being 0.001 to 30%. This passage is not restricted by any specific condition as to the amounts of the other components. Thus, the introduction in claim 1 of the feature "0.001 to 30%" does not result in addition of subject-matter.

3.2 Claim 1 of the patent differs from claim 1 of the original application also in the indication that the composition is "bleaching" and "in the form of a water-in-oil emulsion".

3.2.1 Several passages of the original application (e.g. claim 1 and page 1, line 11) indicate that the composition contains a bleaching agent. Hence, the introduction of the feature "bleaching" is directly and unambiguously derivable from the original application.

The indication that the composition is a "water-in-oil emulsion" finds a basis in original claim 6 that depends on original claim 1.

3.3 Therefore, the patent meets the requirements of Article 123(2) EPC.

4. Novelty

4.1 The novelty of claim 1 has been contested by the respondent on the basis of example 1 of D3.

The product obtained in this example (see [0057]) contains a discontinuous aqueous phase (A) dispersed in the continuous phase containing the components (B) and

(C). (B) is the polymer GMX-0610, a solid material according to D15. The main components of (C) are water and propylene glycol, i.e. a water soluble substance. Thus, the Board agrees with the appellant that the phase containing (B) and (C) is not a continuous, hydrophobic phase. Furthermore, the product obtained in example 1 of D3 is not a water-in-oil emulsion because there is no oil phase. Hence, claim 1 is novel over D3.

5. Inventive step

5.1 Closest prior art

5.1.1 The patent in suit addresses the problem of providing a product for whitening the teeth with improved bleaching efficacy and good tolerability (see [0003]). Document D11 relates to tooth whitening products and addresses the same problem as the patent in suit (see [0005]). The Board, in agreement with the opposition division considers that D11 is the closest prior art.

5.1.2 The tooth whitening product of D11 is characterised by the fact of having a peroxide concentration of greater than about 7.5 % by weight and a peroxide density of less than about 1.3 mg/cm^2 (see [0006]). In paragraph [0041] it is explained that the composition can be provided in the form of a viscous liquid, paste, gel, solution, or any other state that can form a thin layer. D11 does not disclose any specific example of a tooth whitening composition. The composition of claim 1 of the patent differs from the compositions of D11 at least in that it is in the form of a water-in-oil emulsion.

5.2 Technical problem

5.2.1 D16 provides data on the whitening properties of the water-in-oil composition of example 1 of the patent and of a commercial composition containing the same amount of hydrogen peroxide (composition B). The data indicate that the composition according to the patent has a higher whitening efficacy than composition B.

5.2.2 The Board accepts the respondent's argument that D16 is no evidence of an improvement of the bleaching composition of claim 1 over those of D11. This is because there is no indication that the reference composition B used in D16 has the same features as the compositions of D11.

Thus, the technical problem underlying the invention is the provision of an alternative tooth whitening composition.

5.3 Obviousness

5.3.1 As indicated above, D11 explains in paragraph [0041] that the tooth whitening compositions can be provided in the form of a viscous liquid. This passage specifically mentions pastes, gels and solutions as suitable forms. In the Board's view, the skilled person using D11 as starting point for developing a tooth whitening composition would very likely prepare and test one of the forms specifically mentioned in paragraph [0041].

5.3.2 In the respondent's view, the skilled person would find in document D1 the suggestion to provide the compositions of D11 in the form of a water-in-silicone

emulsion, i.e. a specific type of a water-in-oil emulsion.

It is noted however that there is no reference in paragraph [0041] or in any other part of D11 to emulsions, not to mention water-in-oil emulsions. Nor does D11 refer to compositions containing a silicone oil. Thus, the skilled person would have no motivation to provide the tooth whitening compositions of D11 in the specific form of a water-in-silicone emulsion mentioned in D1.

5.3.3 The Board further considers that the teachings of D11 and D1 differ in several aspects so that the skilled person would not consider to combine these two documents.

D11 aims at the provision of a whitening product that achieves an increased whitening capacity while avoiding problems of soft tissue irritation (see [0005]). This objective is met by a composition having specific peroxide concentration and density which is disposed on a strip sized to cover the surface of one or more teeth (0006]). The strip is worn by the users for relatively short times, such as twice a day for thirty minutes (see [0026]).

D1 addresses instead the problem of providing oral care compositions which can be used to deliver in a sustained release manner a wide range of oral care actives (see first paragraph of page 1 and paragraph bridging pages 5 and 6). These compositions are directly applied to the surface of the oral cavity and remain in place for at least 2 hours, preferably at least 4 hours (page 28, penultimate paragraph).

Furthermore, in order to achieve high peroxide concentrations, the compositions of D11 are very thin, preferably less than 0.2 mm (see [0038]). D1 is silent with regard to the thickness of the composition. However, the indication that the application can be made by the use of a finger (page 28, lines 8-9), suggests that the thickness is not a critical parameter.

5.3.4 With regard to D1, the Board further notes that this document relates to oral compositions that may optionally contain an orally active substance. Bleaching agents are cited on page 17 as an example of an active substance. However, D1 does not disclose a single example of a tooth whitening composition. Example 7, discussed by the respondent in its submissions, concerns a composition containing the antibacterial Triclosan as active substance. Although the composition contains a silicone fluid and the emulsifier Pemulen, there is no indication in example 7 that the composition is in the form of a water-in-silicone oil emulsion. For the reasons explained in point 5.4.1 below, the composition of example 7 is very likely an oil-in-water emulsion.

5.3.5 In summary, D1 is not directed to the same purposes as D11 and as the patent-in-suit. There is also no clear technical link between the teachings of D11 and D1: indeed whereas the focus in D11 is on two specific parameters relating to the whitening agent, namely the peroxide concentration and the peroxide density, D1 concerns the use of a mixture of silicone materials as carrier suitable for a wide range of oral care actives.

Worthy of note appears also the fact that neither D11 nor D1 provides an example of a tooth whitening

composition and that none of these documents unambiguously discloses a water-in-oil emulsion.

Under these circumstances, the Board considers that only with the benefit of hindsight knowledge of the invention the skilled person would have arrived at the subject-matter of the patent by combining the teaching of D11 with that of D1.

5.4 Following an alternative approach, the respondent argues that the subject-matter of the patent would be obvious on the basis of example 7 of D1 considered alone. In its opinion this example describes a water-in-silicone oil emulsion containing the antibacterial Triclosan as active agent. The skilled person would arrive at the subject-matter of the patent by replacing Triclosan with a bleaching substance.

5.4.1 In the Board's view this argument is also unconvincing.

The skilled person facing the problem of providing a tooth whitening composition would more realistically start from a known composition having the same use rather than transforming a composition which is conceived to treat or prevent bacterial infections into a whitening product.

Furthermore, as mentioned in point 5.3.4 above, there is no clear indication in D1 that the composition of example 7 is a water-in-silicone oil emulsion. According to the general teaching of D1, the compositions can take a variety of forms such as water-in-silicone emulsions, oil-in-silicone emulsions or dispersions (page 27, lines 4 to 6). Example 7 contains an emulsifier of the class of the Pemulen polymeric emulsifiers which are described in D12 (see page 1,

lines 6 to 8 and paragraph "Summary" on page 6) as emulsifiers for oil-in-water emulsions. Hence, even if the skilled person were considering to provide the composition of example 7 with a tooth whitening agent instead of Triclosan, he would very likely obtain an oil-in-water emulsion, rather than a water-in-oil emulsion as argued by the respondent.

Thus, the subject-matter of the main request is inventive over example 7 of D1.

5.5 Therefore, the Board concludes that the subject-matter of the patent meets the requirement of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairwoman:

B. Atienza Vivancos S. Albrecht

Decision electronically authenticated