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**Datasheet for the decision  
of 19 April 2021**

**Case Number:** T 2538/17 - 3.3.07

**Application Number:** 11733368.2

**Publication Number:** 2523650

**IPC:** A61K8/44, A61K8/27

**Language of the proceedings:** EN

**Title of invention:**

STABILIZATION OF ZINC OXIDE FILM IN ORAL COMPOSITIONS

**Applicant:**

Colgate-Palmolive Company

**Headword:**

Zinc oxide film in oral compositions / COLGATE

**Relevant legal provisions:**

EPC Art. 56

RPBA 2020 Art. 13(2), 25(3)

**Keyword:**

Inventive step - main request, auxiliary request 2 (no)

Auxiliary request 1 - admitted (no)



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Case Number: T 2538/17 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 19 April 2021**

**Appellant:** Colgate-Palmolive Company  
(Applicant) 300 Park Avenue  
New York, NY 10022 (US)

**Representative:** Wibbelmann, Jobst  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 16 June 2017  
refusing European patent application No.  
11733368.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** A. Usuelli  
**Members:** J. Lécaillon  
A. Jimenez

## **Summary of Facts and Submissions**

- I. The appeal was filed by the appellant (applicant) against the decision of the examining division to refuse European patent application No. 11 733 368.2 (hereinafter "the application").
- II. The decision was based on a main request and one auxiliary request both filed on 11 April 2017.

The independent claims of the main request read as follows:

"1. An oral care composition comprising:  
a zinc oxide entrained in a film;  
an anionic surfactant;  
an amphoteric surfactant; and  
an organic solvent;  
wherein the anionic surfactant is present in an amount from 0.1% to 5% by weight and the organic solvent is polyethylene glycol and is present in an amount from 2% to 3% by weight."

"8. An oral care composition according to any of claims 1 to 7, for use in providing oral health benefits to an oral surface."

In the auxiliary request it was specified that the films were homogeneously distributed in the composition.

- III. The following documents were cited in the International Search Report or submitted by the appellant during the examination proceedings:

D1: US2007/020201

D6: Supplementary experimental data submitted during the examination oral proceedings, "Declaration under 37 C.F.R. §1.132"

IV. The examining division decided in particular as follows:

- (a) The subject-matter of the main request did not involve an inventive step. D1 was considered to represent the closest prior art. The claimed subject-matter differed from the examples disclosed in table I of D1 in that zinc oxide was entrained in a film. No effect resulting from said distinguishing feature had been substantiated. The objective technical problem to be solved thus lay in the provision of an alternative oral care composition. D1 already generally disclosed the option of entraining zinc oxide in a film and incorporating the film in an oral care composition. It would therefore have appeared obvious to the skilled person to modify the examples of Table 1 of D1 by entraining zinc oxide in a film.
- (b) The introduction of the additional distinguishing feature that the films were substantially homogeneously distributed in the oral care composition would not overcome the objection raised for the main request. No particular effect had been shown for said feature either and it was considered as implicitly disclosed in D1. The auxiliary request did consequently also not involve any inventive step.

V. On 13 October 2017, with the statement setting out the grounds of appeal, the appellant filed a main request

and one auxiliary request. These requests corresponded to the requests on which the decision was based.

VI. With the letter of 19 November 2020 the appellant filed a new auxiliary request 1. The former auxiliary request filed on 12 October 2017 was renumbered auxiliary request 2.

VII. The content of the claims upon which the present decision is based can be illustrated as follows:

Claim 1 of the main request read as stated above (see II.).

Claim 1 of auxiliary request 1 corresponded to claim 1 of the main request wherein the article "an" before "organic solvent" was deleted.

Claim 1 of auxiliary request 2 corresponded to claim 1 of the main request with the addition of the feature "wherein the films are substantially homogeneously distributed in the oral care composition".

VIII. Oral proceedings were held on 19 April 2021.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or one of auxiliary requests 1-2 wherein:

- the main request and auxiliary request 2 were filed with the statement setting out the grounds of appeal on 12 October 2017 and correspond to the requests on which the decision under appeal was based, and
- auxiliary request 1 was filed on 19 November 2020.

X. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) Example 6 of D1 represented the closest prior art as it referred to an oral care composition comprising a zinc oxide film, while examples 2-5 described compositions comprising neat zinc oxide nanoparticles. Example 6 of D1 did not disclose a composition comprising polyethylene glycol (PEG) let alone in any specific concentration. The specific concentration of PEG allowed to stabilise the film. The objective technical problem to be solved would thus reside in the provision of an oral care composition with zinc oxide entrained in a film wherein the film had improved stability in said oral care composition. While example 6 of D1 taught that the film could be incorporated in any standard gel formulation toothpaste, D1 did not taught the criticality in terms of film stability of PEG and its amount when used together with an anionic and an amphoteric surfactant. Furthermore, D1 did not provide any teaching of how to adapt the composition of examples 2-5 to incorporate a zinc oxide film instead of neat zinc oxide nanoparticles. The skilled person could thus have modified any of the solvents and/or surfactants or their amounts, in particular in view of the potential film dissolution with organic solvents. Also the difference of structure between neat nanoparticles and nanoparticles entrained in a film would have discouraged the skilled person from combining the teachings of examples 2-5 and example 6 of D1. Finally, even if the skilled person could have combined the film of example 6 with the composition of examples 2-5, which would be merely one of numerous options, this would have led to

compositions comprising propylene glycol which were not according to the claims. As a result the main request fulfilled the requirements of Article 56 EPC.

- (b) Auxiliary request 1 was filed in response to the preliminary opinion of the Board. This request was *prima facie* relevant to address the objections, by clarifying that the sole organic solvent in the composition was PEG in the claimed amount, and it did not significantly change the case. It should therefore be admitted in the appeal proceedings.
  
- (c) Auxiliary request 2 further differed from example 6 of D1 in that the films were substantially homogeneously distributed in the oral care composition. The skilled person would have no reasonable expectation of success in obtaining such a composition when formulating the film of example 6 according to examples 2-5 of D1. Examples 2-5 related to the formulation of neat zinc oxide nanoparticles which differed in many ways from nanoparticles entrained in a film, in particular in terms of surface properties. Besides the skilled person would have been aware that, when following the mixing step described for the preparation of examples 2-5 (see paragraph [0032] of D1), there would be a risk of damaging the film. Auxiliary request 2 therefore met the requirements of Article 56 EPC.

## Reasons for the Decision

### *Main request*

#### 1. Inventive step

##### 1.1 *Closest prior art*

1.1.1 In agreement with the examining division and the appellant, the Board considers D1 to represent the closest prior art.

1.1.2 D1 discloses oral care compositions containing zinc oxide in the form of non-aggregated nanoparticles which may be further entrained in a film (see *inter alia* paragraph [0005]). D1 aims at reducing the amount of zinc oxide used so as to improve organoleptic properties while retaining a desirable activity (see paragraph [0009]). D1 discloses:

- examples (examples 2-5) of oral compositions containing zinc oxide nanoparticles and a vehicle comprising 1.5% by weight of anionic surfactant (sodium lauryl sulfate), 3.0% by weight of polyethylene glycol and an amphoteric surfactant (cocamidopropyl betaine), as well as
- an example (example 6) of a zinc oxide containing film to be incorporated into a standard gel formulation toothpaste.

1.1.3 According to the appellant, the closest embodiment of D1 is example 6, as it discloses a zinc oxide containing film incorporated into a standard gel formulation toothpaste.



## 1.2 *Distinguishing feature*

The subject-matter of the main request differs from example 6 of D1 in the nature of the vehicle. No details as to the vehicle used is provided in example 6 of D1 while claim 1 of the main request specifies that the oral care composition comprises, in addition to the zinc oxide containing film, 0.1% to 5% by weight of an anionic surfactant, an amphoteric surfactant and 2-3% by weight of polyethylene glycol (PEG).

## 1.3 *Technical effect*

No particular effect in comparison with example 6 of D1, *i.e.* an effect linked to the choice of the vehicle, has been substantiated. The experimental data provided in the original application (see example 2 and Figures 1-2) and in D6 substantiate a stabilising effect of the claimed range of PEG concentration in comparison to lower amounts thereof. These results were however obtained for compositions comprising specific anionic and amphoteric surfactants. According to paragraphs [0067]-[0069] of present application, said stabilising effect would be linked to a decreased interaction between zinc oxide (having a net positive charge) and the anionic surfactant. The criticality of both the surfactants and PEG for the stability of the film was further brought forward by the appellant in the letter of 19 November 2020 (see page 4, 5<sup>th</sup> paragraph) and during oral proceedings. It follows that the effect shown for some concentrations of PEG appears to be related to the presence of at least the anionic surfactant. This effect cannot be considered as an effect necessarily occurring in comparison to any "standard gel formulation toothpaste" as defined in example 6 of D1. Furthermore the Board notes that a

stabilising effect of PEG in the claimed concentration range in comparison to higher concentrations, which would support the choice of the upper-end value of the claimed range, has not been experimentally substantiated.

Accordingly no improvement over D1 has been substantiated.

#### 1.4 *Objective technical problem*

1.4.1 It remains that the experimental data mentioned above show that the specific compositions exemplified by the appellant have *per se* a good film stability. It follows that, starting from example 6 of D1, the objective technical problem can be seen as residing in the provision of further oral care compositions comprising zinc oxide entrained in a film having good film stability.

#### 1.5 *Obviousness of the solution*

1.5.1 D1 generally describes oral care compositions comprising non-aggregated zinc oxide nanoparticles which are either incorporated neat or entrained in a film (see paragraphs [0005], [0015], [0016]). D1 does not mention any particular restriction in the way the film should be formulated in an oral care composition nor any potential issues as to its stability in the composition. It merely refers to processing the film to "various known types of commercial products", incorporating the film itself in "other oral care products such as mouthwash, toothpaste,"... (see paragraph [0020]) or incorporating the film into a "standard gel formulation toothpaste" (see paragraph [0034]). Furthermore the vehicle is generally described

in D1 independently of whether the zinc oxide nanoparticles are incorporated neat or entrained in a film and it is defined as "any known or to be developed in the art" (see paragraph [0024]). The skilled person would therefore have learned from D1 that the described zinc oxide film may be introduced in any type of oral care compositions.

1.5.2 As stated above (see 1.1.2), D1 provides in examples 2-5 a detailed description of a specific vehicle which was used to formulate neat zinc oxide nanoparticles. As detailed in the previous paragraph, D1 does not teach that using zinc oxide nanoparticles entrained in a film, instead of neat, would require any particular formulation, such as a particular vehicle. Using the specific vehicle disclosed in D1 (*i.e.* in examples 2-5) would consequently be the first option the skilled person willing to solve the problem posed would consider, instead of looking for further more remote carrier compositions. The skilled person would furthermore recognise that said vehicle is suitable for the formulation of films in general, as it contains white flavored films. Said vehicle comprises the presently claimed excipients in the presently claimed amounts, so that the skilled person willing to solve the problem posed would have arrived at the presently claimed subject-matter without the exercise of inventive skills.

1.5.3 Furthermore, although D1 does not discuss the relevance of PEG (and its amount) for the stability of the film, it discloses examples 2-5 in which the vehicle contains the exact same anionic and amphoteric surfactants and PEG (in the same amount) as the ones defined in claim 1. The skilled person would have no reason to doubt of the stability of these compositions. Furthermore for

the reasons detailed above (see 1.5.2) the skilled person would also assume that the same vehicles were to be equally used for film-containing compositions. Accordingly, the skilled person would have had no concerns regarding stability when using the vehicle of examples 2-5 to formulate the film of example 6 in order to solve the problem posed. Contrary to the opinion of the appellant, the absence of a hint towards a role of PEG and its amount on film stability, would not prevent the skilled person from solving the present objective technical problem in an obvious manner.

1.5.4 The appellant argued that the skilled person would not have combined the teachings relating to compositions comprising neat zinc oxide non-aggregated nanoparticles (*i.e.* examples 2-5) and the teachings relating to compositions comprising zinc oxide films (*i.e.* example 6) for the following reasons:

- (a) Using the vehicle of examples 2-5 would be merely one of several alternatives and the skilled person would have been inclined to use a simpler known vehicle.
- (b) The skilled person would have recognised that the vehicle of examples 2-5 had been developed for neat nanoparticles and would not be adapted for nanoparticles entrained in a film. In particular organic solvents could have the potential of dissolving the film. Hence the skilled person may have been tempted to remove PEG or reduce its amount. Furthermore in view of the difference in weight between neat nanoparticles and a film containing nanoparticles, the skilled person would have introduced a higher weight of film to maintain the useful amount of zinc oxide, leading to lower

relative amounts in % by weight of surfactant and PEG. In particular the skilled person would not have replaced the 0.1% by weight of neat nanoparticles of example 2 by 0.1% by weight of film because this would have implied a too low amount of zinc oxide.

(c) Zinc oxide nanoparticles and zinc oxide films have different surface properties and different size, as discussed in paragraphs [0032] and [0034] of D1.

1.5.5 The Board cannot share this view.

Regarding point (a), the Board notes that the fact that there might be other (not specifically defined) options to formulate the film of example 6 has no bearing on the obviousness of the present option. Furthermore, in the present case, the solution offered by combining the examples of D1 would be at least one of equally likely options, if not the most straightforward one, as it does not require any combination with common general knowledge or a further document.

In relation with point (b), the Board observes that, as already stated above, the formulations of examples 2-5 do already contain white, flavored films, *i.e.* films containing an active principle (namely the flavor). The skilled person would hence not have derived from said examples that the vehicle would not be suitable to formulate a film in general, on the contrary. Moreover the Board observes that the film of example 6 is based on a water soluble polymer (HPMC) and thus *a priori* suitable for use together with PEG. This is actually confirmed by the present application which mentions HPMC in a list of suitable polymers for the preparation of the film (see paragraph [0032]). Finally regarding

the issue of the amount of zinc oxide containing film added in the formulation, the Board notes that the amount of neat zinc oxide nanoparticles in examples 2-5 of D1 actually varies from 0.3 to 2% by weight while the amounts of surfactants and PEG remain constant. There is therefore no incentive from table I of D1 to modify the weight amount of the excipients when varying the weight of zinc oxide. In this context the Board furthermore observes that the present claims do not define any minimum amount of zinc oxide and example 1 of the present application discloses itself a formulation containing a low amount of zinc oxide containing film (0.3% by weight).

Concerning point (c), as detailed above (see 1.1.2 and 1.5.2), the Board is of the opinion that D1 actually describes the incorporation of neat non-aggregated zinc oxide nanoparticles or the incorporation of non-aggregated zinc oxide nanoparticles entrained in a film into oral care compositions as equally relevant alternatives. While the difference in surface properties and size between those two options are indeed mentioned in D1, there is no indication that this difference has a consequence on the vehicle to be used.

- 1.5.6 Besides the appellant argued that even by combining said teachings one would not arrive at the subject-matter of present claim 1. According to the appellant, the obtained formulations would be excluded from the scope of present claim 1 because they would contain propylene glycol. The present wording of claim 1 would indeed exclude formulations containing a further organic solvent.

1.5.7 The Board agrees that propylene glycol is not defined as an essential feature of claim 1 of the main request nor is it contained in the exemplified compositions of present application. The Board can also follow the interpretation of the appellant that the organic solvent listed in present claim 1 has been limited to PEG in a given amount. However, the use of the term "comprising" in claim 1 of the main request does not exclude the presence of any further components, such as propylene glycol, which is incidentally described in D1 as a humectant. The Board is therefore of the opinion that the present claim 1 does not exclude the presence of propylene glycol.

1.6 Accordingly the main request does not fulfill the requirements of Article 56 EPC.

*Auxiliary request 1*

2. Admittance

2.1 Auxiliary request 1 was filed on 19 November 2020, *i.e.* after notification of the summons to oral proceedings on 24 July 2020. Its admittance must be decided on the basis of Article 13(2) RPBA 2020 (Article 25(3) RPBA 2020).

2.2 According to the appellant this request was filed in response to the preliminary opinion of the Board of 7 October 2020 and would *prima facie* overcome the objections. Said request would make clear that no other organic solvent than PEG can be present in the claimed composition and would thus not significantly change the case.

2.3 The Board observes that the issue of whether the presence of propylene glycol in the prior art composition represented a distinguishing feature had already been mentioned in the first instance decision (see paragraph 12.7) as well as in the statement setting out the grounds of appeal (see page 3). This point does therefore not constitute a new objection raised by the Board in its preliminary opinion. The appellant did not provide further arguments in support of the admittance of the present request. The Board is therefore of the opinion that there are, in the present case, no exceptional circumstances which would justify to admit this request into the appeal proceedings.

2.4 Auxiliary request 1 is therefore not admitted into the appeal proceedings (Article 13(2) RPBA 2020).

*Auxiliary request 2*

3. Inventive step

3.1 Claim 1 of auxiliary request 2 contains the further feature according to which the films are substantially homogeneously distributed in the oral care composition.

3.2 This feature constitutes a further distinguishing feature versus example 6 of D1, so that the subject-matter of claim 1 of auxiliary request 2 differs from the compositions of D1 in that:

- (i) zinc oxide is entrained in a film, and
- (ii) the films are substantially homogeneously distributed in the oral care composition.



- 3.3 The distinguishing feature (i) is the same as in the case of the main request. The considerations developed above thus apply *mutatis mutandis*.
- 3.4 Concerning feature (ii), the Board notes that no particular effect directly resulting from said feature has been substantiated.
- 3.5 The Board consequently considers that the objective technical problem to be solved remains the same as for the main request, namely the provision of further oral care compositions comprising zinc oxide entrained in a film having good film stability.
- 3.6 The Board observes that in the absence of any particular effect linked to the homogeneous distribution of the films, this feature appears to have been arbitrarily introduced to further distinguish the claimed subject-matter from the one disclosed in D1. The potential advantages, *inter alia* in terms of constant dose, achieved by said feature are immediately apparent for the skilled person. Besides D1 already mentions that the zinc oxide nanoparticles in examples 2-5 are mixed "until a homogeneous mixture is formed" (see paragraph [0032]) . It would therefore have appeared obvious to the skilled person modifying the compositions of example 6 of D1 by using the formulation of examples 2-5 to maintain this homogeneity.
- 3.7 The appellant argued that the skilled person would have had no expectation of success in doing so in view of the large dimensions of the film flakes disclosed in D1 (see example 6 paragraph [0034]) and the difference in surface properties between films and neat nanoparticles.

- 3.8 The appellant did however not explain why the bigger size of film flakes would necessarily lead to less chances of success in terms of homogeneous distribution. While the size of the particles may indeed play a role, surely further parameters (density, mixing conditions, type of distribution *i.e.* suspension, dispersion,...) are also involved. It is furthermore stated in the present patent application itself that "the size of the fragments is not critical" and fragments up to 13 mm long are disclosed (see paragraphs [0039]-[0040]). In the Board's view a skilled person would have been aware of these potential issues and would, if necessary, have routinely adapted the mixing conditions so as to maintain the homogeneous distribution defined in examples 2-5.
- 3.9 Finally , during oral proceedings, the appellant stated that a skilled person would not have applied the step of mixing the formulation until obtaining a homogeneous mixture described in examples 2-5 to the film of example 6 due to the risk of damaging the film.
- 3.10 The Board observes that said homogenisation step in examples 2-5 is however not restricted in terms of physical parameters to be applied upon mixing. Furthermore it is stated in paragraph [0020] of D1 that the film may be processed in various types of known products such as film flakes or strips, *i.e.* film fragments. The Board is therefore of the opinion that the skilled person would be aware of the issue of sensitivity of a film to mechanical damages and would thus, if necessary, routinely adapt the film (such as by preparing fragments) and/or the mixing process to avoid such damages while following the process described in examples 2-5 of D1. In any case the

skilled person would not consider a mixing step *per se* as not suitable for a composition comprising a film.

3.11 As a result, auxiliary request 2 does not involve an inventive step.

## Order

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated