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**Datasheet for the decision  
of 15 May 2020**

**Case Number:** T 2519/17 - 3.3.07

**Application Number:** 09747658.4

**Publication Number:** 2313068

**IPC:** A61K8/25, A61Q11/00

**Language of the proceedings:** EN

**Title of invention:**

ORAL COMPOSITIONS AND USES THEREOF

**Applicant:**

Colgate-Palmolive Company

**Headword:**

ORAL COMPOSITIONS AND USES THEREOF/Colgate-Palmolive Company

**Relevant legal provisions:**

EPC Art. 83, 84, 54, 111(1)  
EPC R. 111(2)  
RPBA 2020 Art. 11

**Keyword:**

Main request - Sufficiency of disclosure (Yes)  
Main request - Clarity (Yes)  
Remittal to the examining division



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 2519/17 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 15 May 2020**

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

**Representative:** Wibbelmann, Jobst  
Wuesthoff & Wuesthoff  
Patentanwälte PartG mbB  
Schweigerstrasse 2  
81541 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 23 June 2017  
refusing European patent application No.  
09747658.4 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** A. Uselli  
**Members:** D. Boulois  
Y. Podbielski

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division to refuse European patent application n° 09 747 658.4.
- II. The decision was a decision on the state of the file based on the communication of the examining division dated 14 December 2016 based on the set of claims filed with letter of 20 August 2015 and the report of a telephonic conversation dated 11 May 2017 based on the set of claims filed with letter of 11 April 2017.

(a) Claim 1 of the set of claims filed with letter of 20 August 2015 read:

"1. An oral composition comprising an orally-acceptable carrier and a silica abrasive consisting essentially of a silica compound having an average particle size of from 5  $\mu\text{m}$  to 20  $\mu\text{m}$  and an Einlehner hardness of from 6 to 9, wherein Einlehner hardness is measured per 174,000 revolutions in 120 minutes with a Brass screen and is of a slurry of 100g silica abrasive in 1L water, wherein the silica abrasive has an oil absorption of from 80cc/100g to 100cc/100g and a  $d_{10}$  of from 2.5  $\mu\text{m}$  to 2.9  $\mu\text{m}$ ; and wherein the composition has a pellicle cleaning ratio of from 80 to 105".

Claim 1 of the set of claims filed with letter of 11 April 2017 read, with the modifications shown in bold:

"1. An oral composition comprising an orally-acceptable carrier and a silica abrasive consisting essentially of

a silica compound having an average particle size of from 5  $\mu\text{m}$  to 20  $\mu\text{m}$  and an Einlehner hardness of from 6 to 9, wherein Einlehner hardness is measured per 174,000 revolutions in 120 minutes with a Brass screen and is of a slurry of 100g silica abrasive in 1L water, wherein the silica abrasive has an oil absorption of from 80cc/100g to 100cc/100g and a  $d_{10}$  of from 2.5  $\mu\text{m}$  to 2.9  $\mu\text{m}$ ; and wherein the composition has a pellicle cleaning ratio of from 80 to 105, **wherein the composition has a radioactive dentin abrasion of less than 150 and a PCR/RDA ratio of from 0.5 to 1.5**".

III. According to the communication dated 14 December 2016 based on the set of claims filed with letter dated 20 August 2015, claim 1 did not meet the requirements of Article 123(2) EPC in view of the term "120 minutes". Moreover, the claimed invention did not meet the requirements of Articles 83 and 84 EPC, in view of the parameter of the pellicle cleaning ratio (PCR).

According to the examining division, the matter for which protection was sought was not clearly defined. The claim attempted to define the subject-matter in terms of the result to be achieved, which merely amounted to a statement of the underlying problem, without providing the technical features necessary for achieving this result. It was clear that the cleaning / polishing efficacy of the composition was reflected in the PCR. However, merely stating the desired PCR range only set out what was to be desired, and not how to achieve this.

The skilled person was thus faced with an undue burden of determining which compositions would have the desired PCR. PCR may be influenced by many components of such a composition. Thus extensive testing would be

necessary in order to be able to carry out the invention across the scope of the claim. Thus there was an insufficiency of disclosure.

Moreover, according to the examining division novelty had not conclusively been established as set out in at least the earlier communication of 25.02.2015.

- IV. According to the report of the consultation by telephone dated 11 May 2017 based on the set of claims filed with letter of 11 April 2017, the amendments to the claims complied with Article 123(2) EPC. However, the claimed invention did not meet the requirements of Article 84 EPC and Article 83 EPC. Claim 1 now included the following parameters:
- the pellicle cleaning ratio (PCR)
  - the radioactive dentin abrasion (RDA) and the PCR/RDA ratio
  - the  $d_{10}$  value for the silica abrasive.

The matter for which protection was sought was not clearly defined. The claim still attempted to define the subject-matter in terms of the result to be achieved. Merely stating the desired PCR and RDA range and ratio, set out what was to be desired, and not how to achieve this.

PCR and RDA might be influenced by many components of the composition, and not just the single silica abrasive as presently defined. Even if only the presently defined silica was present as abrasive affecting the PCR and RDA, the description as filed did not give the skilled person sufficient teaching as to how to find further silicas which would be suitable to meet the defined requirements.

It was not disputed that the RDA and PCR might be measured. This was however not the issue. There was one single commercial product mentioned in the application, which met the requirements of claim 1. However, commercial products might change over time, and it was not necessarily the case that the product as described in the application would always meet the requirements of the claim. Thus, extensive testing would be necessary in order to be able to carry out the invention across the scope of the claim. Thus there was an insufficiency of disclosure.

As regards novelty, it had not conclusively been established with regard to the documents which used Zeodent 113 or Zeodent 115, as set out in at least the communication of 25 February 2015.

V. The applicant (hereinafter the appellant) filed an appeal against said decision. With the statement of grounds of appeal dated 20 October 2017, the appellant filed a main request and auxiliary requests I-III.

Claim 1 of the main request corresponds to claim 1 filed on 11 April 2017. With the exception of a correction of a mistake in claim 4, claims 2 to 6 of the main request correspond to claims 2 to 6 of the request filed on 11 April 2017.

VI. A communication expressing the board's preliminary opinion was sent to the applicant.

VII. The oral proceedings were held by videoconference on 15 May 2020.

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

The claimed invention was sufficiently disclosed. The silica was defined by a certain number of parameters which were all known and measurable. Said silica was commercially available and could anyway be prepared in a routine way; moreover, silica products were usually characterized by the same parameters.

The invention was not about a new silica, but about a known silica. There were patents and literature which showed how to prepare such a product. This was explicitly demonstrated in document US 5,651,958 which was cited in the description of the present application in paragraph [0022]. The silica defined therein corresponded to the silica used in the present invention and was defined by the same parameters, for which, however, a broader range was given. Further details as regards the process of preparation of such silica and the process parameters were given in US 5,651,958 (see col. 5 and 7). The skilled person therefore knew at the filing date how to prepare such silica which was defined by common parameters. Other documents cited by the examining division also related to the same kind of silica.

As regards the product Grace VP5 used in the present application, even if it happened not to be available anymore, a product with the same characteristics could always be produced on demand by any one of a number of specialised companies.

#### IX. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the Examining Division for further prosecution on the basis of the main request or one of auxiliary requests I to III, all filed

with the statement setting out the grounds of appeal dated 20 October 2017.

## **Reasons for the Decision**

### 1. Main Request - Article 123(2) EPC

The main request essentially corresponds to the request filed by the appellant on 11 April 2017, during the examination proceedings. The Board concurs with the finding of the examining division that this request complies with the requirements of Article 123(2) EPC (see point IV above).

### 2. Main request - Article 83 EPC

2.1 The examining division asserted in its communications forming the decision on the state of the file essentially that extensive testing were necessary in order to carry out the invention with regard to both the silica abrasive and the composition containing it, since the only example was a commercial product which might change over time, and it was not necessarily the case that the product as described in the application would always meet the requirements of claim 1; moreover, the description as filed did not give the skilled person sufficient teaching as to how to find further silicas which would be suitable to meet the defined requirements.

2.2 The description of the patent application gives indeed one unique working embodiment that meets the requirements of claim 1. Said abrasive silica used in the compositions according to the claimed invention is known under the trade name GRACE VP5; example 1 of the application shows that said commercial product GRACE



VP5 possesses the claimed properties of oil absorption, mean particle size,  $d_{10}$  and Brass Einlehner hardness parameters (see in particular Table 1). Example 2 gives furthermore the PCR and RDA values, as well as the PCR/RDA ratios, for the silica GRACE VP5 at different slurry dilutions. A 20% and 30% slurry of GRACE VP5 is shown to meet the ratio criteria as defined in claim 1 of the main request. Examples 1 and 2 of the patent application show that the nature of the silica abrasive is the essential element for the claimed oral composition, since the PCR and RDA parameters directly depend on said silica.

Hence, in the present case, the product designated by the trademark GRACE VP5 is essential for carrying out the invention. Therefore, the question arises whether this product will remain available during the whole lifetime of the patent, or, if this is not the case, whether the skilled person would be able to prepare it.

2.3 In this regard, the appellant pointed out to paragraph [0022] of the present description in which reference is made to the patent application US 5,651,958. This document is cited as a reference for the measurement of the PCR parameter and relates to a dentifrice composition comprising a silica abrasive defined in column 2, lines 25-61 as follows (emphasize added by the Board):

"a precipitated silica, said precipitated silica being a low structure precipitated silica having a narrow particle size range distribution of soft particles and having **a mean value (MV) particle size ranging from 8 to 14 microns, an oil absorption ranging from 60 to 120 cc/100 g,** and a mercury intrusion (HGI) void volume of 1.0 to 4.0 cc/g; said precipitated silica, when formulated into a dentifrice, having a **Pellicle**

**Cleaning Ratio (PCR) of from 70 to 140 and a Radioactive Dentin Abrasion (RDA) value of from 60 to 130, and wherein the ratio of said PCR to said RDA is at least 1:1".**

Claim 1 of US 5,651,958 defines the silica by repeating again some of the parameters:

" a precipitated silica, said precipitated silica being a low structure precipitated silica having a narrow particle size range distribution of soft particles and having **a mean value (MV) particle size ranging from 8 to 14 microns, an oil absorption ranging from 60 to 120 cc/100 g,** and a mercury intrusion (HGI) void volume of 1.0 to 4.0 cc/g; said precipitated silica, when formulated into a dentifrice, having a **Pellicle Cleaning Ratio (PCR) of from 70 to 140 and a Radioactive Dentin Abrasion (RDA) value of from 60 to 130;** and wherein **the ratio of said PCR to said RDA is at least 1.1;** and wherein, as the particle size in microns increases in said silica, the RDA value remains substantially constant".

As to the claimed ratio of pellicle cleaning ratio (PCR)/radioactive dentin abrasion(RDA), said document US 5,651,958 confirms furthermore that this ratio is known and used in the field of dentifrice, and that the claimed ratio of 0.5 to 1.5 is also common, as disclosed for instance in the paragraph bridging columns 7 and 8:

"The PCR/RDA ratio is used to determine the relative ratio of cleaning and abrasion characteristics of a dentifrice formulation. Commercially available dentifrice formulations generally have a PCR/RDA ratio in **the range of 0.5 to below 1.0.** The amorphous silicas used in the compositions of the present invention provide PCR to RDA ratios to dentifrice formulations of

greater than 1, usually in **the range of 1.20 to 1.60**, but more preferably in the range 1.25 to 1.50."

US 5,651,958 does not disclose the  $d_{10}$  of the silica. This is however a measurable parameter of common use; in the present case, the diameter of the particles is comprised between 2.5  $\mu\text{m}$  to 2.9  $\mu\text{m}$  with 10% or less of particles outside of this range.

The abrasive silica defined in US 5,651,958 is therefore defined by the same parameters as those used in claim 1 of the main request and the description of the present application, namely the mean particle size, the oil absorption, the Einlehner hardness, the PCR and the RDA. The ranges of values of said parameters of the silica abrasive in US 5,651,958 are slightly broader than the ranges of values of the parameters for the claimed invention, but are nevertheless very close. The disclosure of US 5,651,958 shows therefore that the general type of abrasive silica used for the present invention is known.

Moreover, document US 5,651,958 gives in column 7, lines 3-40, and in claim 11, explicit indications how to prepare the type of silica abrasive disclosed therein, with references to general methods given in several referenced prior art documents, and more specific reaction parameters to be used.

- 2.4 The disclosure of the document US 5,651,958 therefore proves that the general type of silicas used for the invention of the present application and the methods for preparing it were known and available to the skilled person at the filing date of the patent application. The claimed abrasive silica is therefore sufficiently identified in the description to enable

the invention to be carried out by the skilled person and the requirements of sufficiency of disclosure are therefore met.

Furthermore, in view of the disclosure of US 5,651,958, the Board finds convincing the appellant's argument that such general kind of silica may be prepared by a routine process and that a skilled person would not find it difficult to control all the process parameters to prepare it; claim 11 of US 5,651,958 gives for instance an explicit disclosure of a repeatable method of preparation. Hence, even if it is true that there is no guarantee that the properties and composition of the commercial product GRACE VP5 will remain unchanged during the lifetime of the patent, a skilled person will always be in a position to obtain the abrasive silica of the present application either by having it prepared on demand or by preparing it himself.

2.5 Consequently, the claimed invention is sufficiently disclosed and the main request meets the requirements of Article 83 EPC.

3. Main request - Article 84 EPC

3.1 According to the communications of the examining division, the claimed subject-matter did not meet the requirements of Article 84 EPC, since the matter for which protection was sought was not clearly defined and the claim attempted to define the subject-matter in terms of the result to be achieved.

3.2 The subject-matter of claim 1 of the main request relates to a composition comprising essentially an abrasive silica defined by several parameters:  
- average particle size

- Einlehner hardness
- oil absorption
- $d_{10}$
- PCR
- RDA
- PCR/RDA ratio.

All these parameters are known and usual in the field of dentifrice, in particular in connection with the use of abrasive silica. They are also measurable, as was acknowledged by the examining division; this is confirmed by the teaching of document US 5,651,958 which is disclosed in the description of the patent application and document US 5,658,553 cited in the same passage as US 5,651,958 (see for instance claim 9 of US 5,658,553). Furthermore, methods for the measurement of all the parameters are described in paragraphs [0016] to [0023] of the description.

- 3.2.1 The use of the parameters of average particle size, Einlehner hardness, oil absorption and  $d_{10}$ , and in particular the parameters of PCR and RDA appears to be one of the few possible ways for characterizing abrasive silica and for distinguishing a given abrasive silica from another given abrasive silica. Such parameters are commonly used by the silica manufacturers to characterize the physico-chemical properties of their products.
- 3.2.2 As regards more specifically the claimed ratio of PCR/RDA, the description indicates that the values of PCR and RDA are directly dependent on the physical properties of the abrasive silica. This is particularly evident when considering the experiments of examples 1 and 2 of the patent application which show that a slurry of a silica having the average particle size,

Einlehner hardness, oil absorption and  $d_{10}$  as defined in claim 1, provides the desired values of PCR and RDA. Consequently, all the technical features necessary for achieving the claimed PCR/RDA ratio are present in claim 1.

3.3 Apart from the general statements present in the communications which form the appealed decision on the state of the file, there is no further argument given by the examining division which could credibly call into question the requirements as regards Article 84 EPC.

3.4 Hence, the subject-matter of claim 1 of the main request is clear and the main request meets the requirements of Article 84 EPC.

4. Main request -Novelty

4.1 As regards novelty, the two communications which form the appealed decision on the state of the file, refer to documents disclosing specific silicas, i.e Zeodent 113 and Zeodent 115, without naming specifically said documents or citing their relevant passages. The two communications just make reference to a third communication dated 25 February 2015 as regards the novelty objection.

4.2 This "February 2015 communication" was however based on another and different set of claims filed with letter of 8 May 2014, and therefore it is not clear how the objections raised in this earlier "February 2015 communication" can still apply to the latest versions of the claims on which the two communications forming the decision on the state of the file were based.

4.3 Moreover, claim 1 and dependent claims 3-5 of the set filed with letter of 8 May 2014 read as follows:

"1. An oral composition comprising an orally-acceptable carrier and a silica abrasive consisting essentially of a silica compound having an average particle size of from 5  $\mu\text{m}$  to 20  $\mu\text{m}$  and an Einlehner hardness of from 6 to 9, wherein Einlehner hardness is measured per 174,000 revolutions with a Brass screen and is of a slurry of 100g silica abrasive in 1L water, wherein the silica abrasive has an oil absorption of from 80cc/100g to 100cc/100g and a  $d_{10}$  of from 2.5  $\mu\text{m}$  to 2.9  $\mu\text{m}$ ".

3. The composition of any one of the preceding claims having a pellicle cleaning ratio of from 80 to 105.

4. The composition of any one of the preceding claims having a radioactive dentin abrasion of less than 150.

5. The composition of any one of the preceding claims having a PCR/RDA ratio of from 0.5 to 1.5."

In said "February 2015 communication", a novelty objection was raised only against claim 1 of the request on file (filed with letter of 8 May 2014), while no novelty objections were raised against the subject-matter of dependent claims 3-5.

The features of dependent claims 3-5 are however now in the latest versions of the claims on which the communications forming the decision on the state of the file are based, and said subject-matter is objected to for lack of novelty with reference to the February 2015 communication, while before they were not. It is therefore not possible to understand from the communications forming the decision on the state of the

file why the objections of lack of novelty still apply to said latest set of claims. Moreover, these features are included in claim 1 of the current main request.

From all points above, it is not clear how and to what extent the novelty objections raised in the earlier communication apply or not to the latest version of the claims. If they did apply, it is not clear which facts and arguments the examining division considered and on which reasons it based its conclusion that the subject-matter of claim 1 was not novel.

In the Board's view, that part of the decision which concerns novelty is not reasoned (Rule 111(2) EPC). In any case, this part of the decision does not relate to the same subject-matter as the current main request.

5. Remittal to the examining division

The sole reasoned grounds for the refusal set out in the decision under appeal, namely a lack of sufficient disclosure and a lack of clarity, are not justified.

The decision under appeal does not comprise a reasoned decision as regards novelty and does not address inventive step. Furthermore, the considerations made by the examining division in relation to the requirement of novelty, concerns a set of claim different from the main request pending before the Board.

Under Article 111(1) EPC, the Board may either proceed further with the examination of the application, in particular with respect to Articles 54 and 56 EPC, or remit the case to the examining division for further prosecution.



Since the present appeal was pending on 1 January 2020, the revised version of the RPBA applies (OJ EPO 2019, A63), subject to the transitional provisions set out in Article 25 of said RPBA. In particular Article 11 RPBA 2020 is applicable. Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The Board holds that such special reasons are apparent in the present case because the examining division has not taken an appealable decision on essential outstanding issues with respect to Articles 54 and 56 EPC. As recalled in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of the application. Consequently, in the present case, Article 11 RPBA 2020 cannot be interpreted to mean that that the Board should carry out a full examination of the application for compliance with the requirements of Articles 54 and 56 EPC for which no reasoned decision of the first instance exists yet.

Under these circumstances, the Board considers it appropriate to allow the appellant's request for remittal of the case to the examining division (Article 111(1) EPC). Accordingly, the Board can accede to the appellant's request that the appealed decision be set aside and that the patent application be remitted to the examining division for further prosecution.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated