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**Datasheet for the decision
of 12 May 2026**

Case Number: T 0633/24 - 3.3.07

Application Number: 16756876.5

Publication Number: 3484437

IPC: A61K8/27, A61K8/49, A61Q11/00

Language of the proceedings: EN

Title of invention:
DENTIFRICE INCLUDING ZINC AND BLUE DYE OR PIGMENT

Patent Proprietor:
Colgate-Palmolive Company

Opponent:
Unilever IP Holdings B.V./ Unilever
Global IP Limited

Headword:
Dentifrice with zinc and blue dye/COLGATE

Relevant legal provisions:
EPC Art. 53(c), 123(3)
RPBA 2020 Art. 13(2)

Keyword:

Exceptions to patentability - method for treatment by therapy
Amendments - change of category
Amendment after communication pursuant to Article 13(2) RPBA -
taken into account (no)

Decisions cited:

G 0001/03, T 1635/09, G 0002/08



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Case Number: T 0633/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 12 May 2026

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted/
electronically transmitted on 7 March 2024
concerning maintenance of the European Patent
No. 3484437 in amended fo rm.**

Composition of the Board:

Chairman A. Usuelli
Members: M. Steendijk
L. Basterreix

Summary of Facts and Submissions

- I. European patent 3 484 437 ("the patent") was granted with fifteen claims.

Claim 1 as granted defines:

"Use of a whitening dentifrice composition for whitening a tooth surface in a human or animal, wherein the whitening dentifrice composition comprises:

- a blue dye;
- a zinc salt, wherein the whitening dentifrice composition provides a greater whitening benefit to a tooth surface in comparison to a dentifrice composition that does not contain the zinc salt;
- and
- an orally acceptable vehicle."

Claim 8 as granted defines:

"Use of a whitening dentifrice composition for whitening a tooth surface in a human or animal, wherein the whitening dentifrice composition comprises:

- a blue dye;
- a zinc salt present in an amount from about 0.1 wt% to about 5 wt%;
- water in an amount from about 25% to about 80%, wherein the whitening dentifrice composition including the zinc salt provides a greater initial whitening benefit and a longer-lasting whitening benefit to a tooth surface than a dentifrice composition including the same amount of water and no zinc salt; and
- an orally acceptable vehicle."

Claim 13 as granted defines:

"A method for whitening a tooth surface in a human or animal, the method comprising:

applying a whitening dentifrice composition to the tooth surface, wherein the whitening dentifrice composition comprises:

a blue dye;

zinc lactate present in an amount from about 0.1 wt% to about 5 wt%, wherein the whitening

dentifrice composition provides a greater whitening benefit to the tooth surface than a dentifrice composition including other zinc salts or no zinc

salt; and

an orally acceptable vehicle."

Claim 15 as granted defines:

"Use of zinc lactate in a whitening dentifrice composition for providing greater whitening effect to the tooth surface, wherein the whitening dentifrice composition comprises a blue dye or blue pigment, wherein the blue pigment has a blue to blue-violet color with a hue angle in the CIELAB system ranging from 200 degrees to 320 degrees."

- II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as filed.

The opposition division decided that the patent as amended in accordance with auxiliary request 7,

submitted during the oral proceedings held on 30 January 2024, met the requirements of the EPC.

This interlocutory decision was based on the patent as granted (main request), auxiliary requests 1-6 filed on 29 November 2023 and auxiliary request 7 filed on 30 January 2024.

According to the decision under appeal:

- (a) The uses and methods defined in granted claims 1, 8, and 13 related to a dentifrice composition comprising a blue dye and a zinc salt intended for whitening a tooth surface in humans or animals, which involved cleaning the teeth by brushing. Any method that included tooth brushing constituted a therapeutic indication, which could not be separated from any resulting or intended cosmetic effect.

Consequently, the patent as granted did not comply with Article 53(c) EPC.

The same objection applied to auxiliary requests 1-6.

- (b) The claims of auxiliary request 7 were restricted to a dentifrice composition wherein the zinc salt is zinc lactate, reformulated as a composition for use under Article 54(5) EPC. The request was admitted because it directly addressed the objection under Article 53(c) EPC, which had been raised for the first time in the annex to the summons to oral proceedings, and did not unduly disadvantage the opponents.

Auxiliary request 7 complied with Article 123(2) EPC. In the light of G 2/08 the conversion of the claims relating to a medical use to the format of Article 54(5) EPC was not objectionable under Article 123(3) EPC.

Auxiliary request 7 was not objectionable under Article 84 EPC and also complied with the provisions of Articles 83, 54 and 56 EPC.

III. The patent proprietor and the opponent filed appeals against the interlocutory decision of the opposition division that the patent as amended in accordance with auxiliary request 7 meets the requirements of the EPC.

IV. With the statement of grounds of appeal the patent proprietor requested that the patent be maintained as granted (main request) and filed auxiliary requests 1-11.

The independent claims of auxiliary request 1 correspond to granted claims 1, 8, 13 and 15, except for the specification with respect to granted claims 1 and 8 that the zinc salt is selected from the group consisting of zinc lactate, zinc oxide, zinc phosphate and zinc citrate.

The independent claims of auxiliary request 2 correspond to granted claims 8 and 15, except for the same specification of the zinc salt in granted claim 8 as defined in auxiliary request 1.

The independent claim of auxiliary request 3 corresponds to granted claim 8, except for the specification that the zinc salt is selected from the group consisting of zinc lactate and zinc citrate.

The independent claims of auxiliary request 4 correspond to granted claims 8 and 15, except for the same specification of the zinc salt as in auxiliary request 2 and the definition of the additional feature that the blue dye is comprised in an amount of 0,01% to 0.3% by weight.

The independent claims of auxiliary request 5 correspond to granted claims 1, 8 and 15, except for the specification with respect to granted claims 1 and 8 that the zinc salt is zinc lactate.

The independent claims of auxiliary request 6 correspond to granted claims 1 and 8, except for the specification with respect to granted claims 1 and 8 that the zinc salt is zinc lactate and the definition of the additional feature that the blue dye is comprised in an amount of 0,01% to 0.3% by weight.

The independent claims of auxiliary request 7 correspond to granted claims 1, 8, and 13, which are reformulated to define a whitening composition for use in a method of whitening a tooth surface (instead of a use or method) and wherein with respect to granted claims 1 and 8 the zinc salt is specified as selected from the group consisting of zinc lactate, zinc oxide, zinc phosphate and zinc citrate. Claim 1 of auxiliary request 7 thus defines:

"Whitening dentifrice composition for use in a method of whitening a tooth surface in a human or animal, wherein the whitening dentifrice composition comprises:
a blue dye;
a zinc salt, wherein the zinc salt is selected from the group consisting of zinc lactate, zinc oxide,

zinc phosphate and zinc citrate, wherein the whitening dentifrice composition provides a greater whitening benefit to a tooth surface in comparison to a dentifrice composition that does not contain the zinc salt; and
an orally acceptable vehicle."

The independent claim of auxiliary request 8 corresponds to granted claims 8, except for the same reformulation as a composition for use and the specification of the zinc salt as in auxiliary request 7.

The independent claim of auxiliary request 9 corresponds to the independent claim of auxiliary request 8, except for the further specification of the zinc salt as selected from the group consisting of zinc lactate and zinc citrate.

The independent claim of auxiliary request 10 corresponds to the independent claim of auxiliary request 8, except for the definition of the additional feature that the blue dye is comprised in an amount of 0,01% to 0.3% by weight.

The independent claims of auxiliary request 11 correspond to granted claims 1 and 8, except for the same reformulation as a composition for use as in auxiliary request 7 and the specification that the zinc salt is zinc lactate.

- V. In its communication pursuant to Article 15(1) RPBA, the Board observed *inter alia* that, while the disclosed effect of whitening a tooth surface appears, *per se*, to be purely cosmetic and not in all circumstances inseparably linked to a therapeutic effect, the uses

and method as defined in the claims of the patent and in auxiliary requests 1-6 do not exclude therapy. The Board indicated in this context that, for instance, the embodiments set out in paragraphs [0067]-[0075] of the patent appear to suggest that the claimed uses and method may encompass, or coincide with, methods falling under Article 53(c) EPC. The Board further questioned, with reference to the considerations in T 1635/09, whether auxiliary requests 7-11 complied with Article 123(3) EPC.

VI. With its submission of 10 March 2026, the patent proprietor filed amended description pages for the main request and auxiliary requests 1-6, deleting paragraphs [0067]-[0075] of the patent as granted, as well as new auxiliary requests 12-17, which correspond to auxiliary requests 1-6, except for the introduction of the qualification of the defined uses and method as "cosmetic". Claim 1 of auxiliary request 12 thus defines:

"Cosmetic use of a whitening dentifrice composition for whitening a tooth surface in a human or animal, wherein the whitening dentifrice composition comprises:

a blue dye;

a zinc salt, wherein the zinc salt is selected from the group consisting of zinc lactate, zinc oxide, zinc phosphate and zinc citrate, wherein the whitening dentifrice composition provides a greater whitening benefit to a tooth surface in comparison to a dentifrice composition that does not contain the zinc salt; and

an orally acceptable vehicle."

VII. Oral proceedings were held on 12 May 2026. During the oral proceedings, the Board referred to the

considerations in G 1/03 (Reasons 2.4.1) and questioned whether, insofar as any objection under Article 53(c) arose, the amendments to the description and auxiliary requests 12-17 filed with the patent proprietor's submission of 10 March 2026 were suitable to overcome this objection.

VIII. The arguments of the patent proprietor relevant to the present decision are summarised as follows:

The amendments to the description addressed the objection regarding paragraphs [0067]-[0075], first raised in the Board's communication pursuant to Article 15(1) RPBA. The filing of auxiliary requests 12-17 was likewise responsive to the Board's preliminary observations in this regard. The amendments were straightforward, not complex or contrary to procedural economy, and *prima facie* allowable. The patent proprietor could not have been expected to file the amendments at an earlier stage, in view of the objection by the opposition division that the granted claims implicitly required brushing. Disclaiming therapeutic use by introducing the qualification "cosmetic" only became an option following the Board's preliminary observations in this respect.

The purpose of whitening the tooth surface as defined in the claims as granted and in auxiliary requests 1-6 related to a purely cosmetic effect resulting from the combination of the defined blue dye and the zinc salt. This effect did not require brushing and was not necessarily linked to therapy. In particular, any inherent antibacterial activity of a zinc salt would not necessarily result in a therapeutic effect, for instance where the subject

received antibacterial treatment prior to the application of the defined whitening composition. According to established jurisprudence (Case Law of the Boards of Appeal of the EPO, 11th edition, 2025, I.B.4.5.2), the exclusion from patentability under Article 53(c) EPC for therapeutic methods applied to a claimed non-therapeutic use only if such use is inseparably associated with a therapeutic effect.

The definition of the subject-matter of auxiliary claims 7-11 in the format of Article 54(5) EPC, as a whitening dentrifice composition for use in a method of whitening a tooth surface, did not contravene Article 123(3) EPC, since the subject-matter thereby defined was, in accordance with G 2/08 (Reasons 5.10.4), limited to the specified use. The considerations in T 1635/09 concerned reformulation in the Swiss-type format and did not apply to auxiliary requests 7-11.

IX. The arguments of the opponents relevant to the present decision are summarized as follows:

The amendments to the description and auxiliary requests 12-17 should, in the absence of exceptional circumstances, not be admitted under Article 13(2) RPBA. The argument that these amendments and requests were filed in response to the Board's communication pursuant to Article 15(1) RPBA did not justify their late filing, since they could and should have been filed at an earlier stage.

The uses and method involving a dentifrice for whitening a tooth surface in a human or animal, as

defined in the claims as granted and in auxiliary requests 1-6, were inseparably linked to a therapeutic effect resulting from the presence of the zinc salt in the dentifrice. Moreover, the claims encompassed embodiments in which the whitening of the tooth surface results from the removal of plaque or tartar. This represented a therapeutic effect associated with the use of a dentifrice and specifically intended to be encompassed by the claims, as illustrated by paragraphs [0067]-[0075] of the patent.

The change of category from the use and method claims of the patent as granted to claims directed to compositions for use in a method of whitening a tooth surface in auxiliary requests 7-11 contravened Article 123(3) EPC. The principles set out in G 2/08 did not address such a change of category.

- X. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted. The patent proprietor also requested that the amendment to paragraphs [0067] to [0075] of the patent specification filed with the letter of 10 March 2026 be admitted into the appeal proceedings.

As an auxiliary measure, the patent proprietor requested that the patent be maintained on the basis of one of auxiliary requests 1 to 11 as filed with the statement of grounds of appeal, or auxiliary requests 12 to 17 as filed with the letter of 10 March 2026.

The patent proprietor further requested that the case be remitted to the opposition division for further

examination of the granted use claims and the corresponding auxiliary requests based on use claims.

- XI. The appellants-opponents requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Insofar as relevant to the decision, the opponents further requested that the amendments to the description and auxiliary requests 12-17 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Main request and auxiliary requests 1-6
 - 1.1 Admittance of the amendments to the description
 - 1.1.1 The patent proprietor submitted amendments to the description to be taken into account for the main request relating to the claims as granted and auxiliary requests 1-6. The amendments concerned the deletion of paragraphs [0067]-[0075] of the patent. These paragraphs describe that the dentifrice compositions optionally include one or more further active materials for the prevention or treatment of a condition or disorder of hard or soft tissue of the oral cavity, for treatment of a physiological disorder or condition, or for providing a cosmetic effect, including dental abrasives and anti-tartar agents.

The amendments were filed with the patent proprietor's submission of 10 March 2026, after notification of the Board's communication under Article 15(1) RPBA. The admittance of this amendment to the patent proprietor's appeal case is therefore subject to the provisions of

Article 13(2) RPBA, according to which such an amendment shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

1.1.2 The patent proprietor argued that the amendments to the description addressed an objection regarding paragraphs [0067]-[0075] first raised in the Board's communication under Article 15(1) RPBA.

1.1.3 In section 3 of this communication, the Board addressed the finding in the decision under appeal that the claims as granted did not comply with Article 53(c) EPC. The Board observed that, while the disclosed effect of whitening a tooth surface appears, *per se*, to be purely cosmetic and not in all circumstances inseparably linked to a therapeutic effect, the uses and method as defined in the granted claims of the patent and in auxiliary requests 1-6 do not exclude therapy. In this context, the Board did not raise a new objection in relation to paragraphs [0067]-[0075], but merely indicated that, for instance, the embodiments set out in those paragraphs appear to suggest that the claimed uses and method may encompass, or coincide with, methods falling under Article 53(c) EPC. Notably, the decision under appeal (sections 16.7-16.8) relied on these paragraphs to conclude that, in the claims as granted, the therapeutic effect cannot be separated from the whitening effect.

Moreover, insofar as an objection under Article 53(c) EPC arises from the fact that the granted claims of the patent and auxiliary requests 1-6 do not exclude therapy, the mere deletion of paragraphs [0067]-[0075] from the description is not suitable to

overcome this objection, since the claims define a whitening dentifrice composition in an open manner and those paragraphs merely specify conventional additional ingredients for such compositions.

- 1.1.4 The Board therefore does not recognise any exceptional circumstances within the meaning of Article 13(2) RPBA. Accordingly, the Board decided not to admit the amendments to the description into the appeal proceedings.
- 1.2 Subject matter excluded from patentability under Article 53(c) EPC
 - 1.2.1 According to established jurisprudence (CLBA, 11th ed., 2025, I.B.4.5.2), if the scope defined by the wording of a claim encompasses a use directed to a non-therapeutic effect which is inseparably associated with a therapeutic effect, such a use is excluded from patentability under Article 53(c) EPC. Notably, G 1/03 (Reasons 2.4.1) explains in this context that it may happen that a general claim comprises embodiments which fall under an exception to patentability, whereas the rest is patentable, and that, in such a case, the introduction of a disclaimer is allowable.
 - 1.2.2 Independent claims 1 and 8 as granted relate to the use of a whitening dentifrice composition for whitening a tooth surface in a human or animal.

The Board observes that a mere whitening effect resulting from the deposition of the blue dye from the combination of the blue dye and the zinc salt in the dentifrice appears to represent a purely cosmetic effect, which is not necessarily linked to any therapeutic or related prophylactic effect. As pointed

out by the patent proprietor, any inherent antibacterial activity of the zinc salt comprised in the composition does not necessarily result in a therapeutic effect, in particular where the subject received antibacterial treatment immediately prior to the application of the defined whitening composition.

However, the purpose of whitening the tooth surface as defined in the claims concerns the use of a whitening dentifrice composition which is defined in an open manner to comprise a blue dye and a zinc salt. The defined uses of this whitening dentifrice composition are therefore not confined to a purely cosmetic effect resulting from the deposition of the blue dye. Rather, they encompass embodiments in which the whitening effect, defined as the purpose of the claimed uses, results at least partially from the removal of plaque or tartar. In such embodiments, the defined whitening effect is inseparably linked to the therapeutic or prophylactic effect of plaque or tartar removal conventionally associated with the use of a dentifrice composition, as indeed foreseen in the patent, as illustrated by paragraphs [0067]-[0075]. These embodiments are not excluded from the scope of granted claims 1 and 8, which therefore encompass subject-matter excluded from patentability under Article 53(c) EPC.

The same objection applies *a fortiori* to independent claim 13 as granted, which, being directed to a method for whitening a tooth surface in a human or animal by applying a whitening dentifrice composition and thus relating to treatment steps, encompasses embodiments where whitening is achieved via plaque or tartar removal falling within the scope of Article 53(c) EPC.

Accordingly, the Board concludes that the main request contravenes Article 53(c) EPC.

1.2.3 Auxiliary requests 1-6 include claims defining a use of a whitening dentifrice directed to the same purpose as defined in granted claims 1 and 8. For the same reasons set out in section 1.2.2 above for the main request, auxiliary requests 1-6 likewise contravene Article 53(c) EPC.

2. Auxiliary requests 7-11, Article 123(3) EPC

The claims of auxiliary requests 7-11 define a whitening dentifrice composition for use in a method of whitening a tooth surface in a human or animal, thus involving a change of category compared with the claims as granted, which defined only uses and methods. Notably, the claims of auxiliary requests 7-11 define products for use in a method which is not directed exclusively to a therapeutic effect (see section 1.2.2 above) and may therefore not qualify as purpose-limited product claims within the meaning of Article 54(5) EPC. They are therefore directed to products, with the consequence that the manufacture of the defined products falls within their scope of protection, unlike the granted claims. Accordingly, and in line with T 1635/09 (Reasons 15.1), auxiliary requests 7-11 contravene Article 123(3) EPC.

The patent proprietor's argument based on G 2/08 (Reasons 5.10.4) cannot be followed. The considerations in G 2/08 relied on by the patent proprietor merely concern the new type of purpose-limited product protection introduced under Article 54(5) EPC 2000, which is expressly limited to a specific medical use, in contrast to the existing provision for generic

purpose-limited product protection where the invention relates to the first medical use of a product. These considerations do not address whether a change of category from use or method claims to purpose-limited product claims results in an extension of the scope of protection.

3. Auxiliary requests 12-17, admittance

- 3.1 The claims of auxiliary requests 12-17 correspond to those of auxiliary requests 1-6, except for the introduction of the qualification of the defined uses and method as "cosmetic".

Auxiliary requests 12-17 were filed with the patent proprietor's submission of 10 March 2026, after notification of the Board's communication under Article 15(1) RPBA and thus constitute an amendment to the patent proprietor's appeal case within the meaning of Article 13(2) RPBA.

- 3.2 The patent proprietor's justification for the late filing of auxiliary requests 12-17 is not convincing.

The argument that the patent proprietor could not have been expected to file these requests at an earlier stage, in view of the objection by the opposition division that the granted claims implicitly required brushing, cannot be followed. The patent proprietor had already contested this objection in its submission of 29 November 2023 (see pages 3-4, section II), arguing that the claimed cosmetic use was distinguishable from a therapeutic method. Nothing prevented the patent proprietor from filing the auxiliary requests 12-17 at that stage of the proceedings, which would have allowed

the opposition division to consider these requests in its decision.

As set out in section 1.1.3 above, the Board observed in its communication pursuant to Article 15(1) RPBA that, while the disclosed effect of whitening a tooth surface appears, *per se*, to be purely cosmetic and not in all circumstances inseparably linked to a therapeutic effect, the uses and method as defined in the granted claims of the patent and in auxiliary requests 1-6 do not exclude therapy. This observation can hardly be regarded as constituting exceptional circumstances within the meaning of Article 13(2) RPBA, since it merely reflected the Board's preliminary assessment of the finding in the decision under appeal in view of the patent proprietor's arguments.

The patent proprietor's arguments, that the amendments in auxiliary requests 12-17 are straightforward, not complex or contrary to procedural economy, and *prima facie* allowable, concern criteria relevant under Article 13(1) RPBA rather than exceptional circumstances within the meaning of Article 13(2) RPBA.

In any case, the introduction of the term "cosmetic" is not equivalent to a disclaimer excluding therapeutic methods as envisaged in G 1/03. It is not apparent that the mere introduction of the qualification "cosmetic" is apt to overcome the objection under Article 53(c) EPC, since it does not exclude embodiments in which the whitening effect results from plaque or tartar removal.

3.3 The Board therefore does not recognise any exceptional circumstances within the meaning of Article 13(2) RPBA that justify the admittance of auxiliary requests 12-17. Accordingly, the Board decided not to

admit auxiliary requests 12-17 into the appeal proceedings.

4. Request for remittal

In view of the Board's conclusions that the granted use claims and the auxiliary requests 1-6 contravene Article 53(c) EPC, and the non-admittance of auxiliary requests 12-17, there is no need for remittal, and the corresponding request is no longer relevant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated