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Datasheet for the decision of 8 May 2018

Case Number: T 1748/15 - 3.3.07

Application Number: 08735787.7

Publication Number: 2131806

IPC: A61K8/19, A61K8/21, A61K8/27, A61Q11/00

Language of the proceedings: EN

Title of invention:
Oral care composition comprising particulate zinc oxide

Patent Proprietor:
Glaxo Group Limited

Opponent:
Colgate-Palmolive Company

Headword:
Oral care composition/ GLAXO

Relevant legal provisions:
EPC Art. 54(2), 54(5), 100(b), 56, 123(2)

Keyword:
Novelty - main request (no)
Inventive step - auxiliary request 1 (no)
Auxiliary request 2 - meets the requirements of the EPC (yes)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Decisions cited:
G 0003/14

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Case Number: T 1748/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 8 May 2018

Appellant: (Opponent)	Colgate-Palmolive Company 300 Park Avenue New York NY 10022-7499 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Respondent: (Patent Proprietor)	Glaxo Group Limited 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Representative:	Morris, Miriam Elizabeth GlaxoSmithKline Global Patents (CN925.1) 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 July 2015 concerning maintenance of the European Patent No. 2131806 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 2 131 806, based on European patent application No. 08735787.7, was opposed on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

The following documents were among those cited during the first-instance proceedings:

D1: US 6,471,946
D2: US 2007/0020201
D7: WO 2004/054529
D8: WO 00/59460

II. The appeal of the opponent (hereinafter: the appellant) lies against the decision of the opposition division according to which the subject-matter of auxiliary request 1 met the requirements of the Convention. The decision was based on the patent as granted as main request and on auxiliary request 1 filed during the oral proceedings held on 23 April 2015.

Claim 1 of the auxiliary request considered by the opposition division to meet the requirements of the EPC read as follows:

"1. An oral care composition comprising nanoparticulate zinc oxide in the absence of palatinit for use in a method of helping to prevent, inhibit, and/or treat dental erosion and/or tooth wear".

The opposition division held that claim 1 of auxiliary request 1 was novel over D1 since this document did not make available the use of compositions containing zinc

oxide in nanoparticulate form and without palatinit in the treatment of dental erosion and/or tooth wear.

D7 was the closest prior art for the assessment of inventive step. Claim 1 of auxiliary request 1 differed from the disclosure of D7 in the indication that zinc oxide was in nanoparticulate form. On the basis of the experimental data disclosed in example 7, the technical problem was the provision of compositions containing zinc oxide with an improved anti-erosion effect. Only documents D1 and D8 related to the problem of treating dental erosion. However, none of these documents suggested using the compositions defined in claim 1 for this therapeutic application. The subject-matter of auxiliary request 1 was therefore inventive.

III. The opponent lodged an appeal against the decision and requested that the decision be set aside and the patent be revoked. In the reply to the appeal of the opponent, the patent proprietor (hereinafter: the respondent) requested to dismiss the appeal and filed an auxiliary request.

IV. On 20 March 2018, the Board issued a communication pursuant to Article 15(1) RPBA. It observed *inter alia* that one of the issues to be considered at the oral proceedings was whether the expression "tooth wear" was clearly recognised to indicate a pathological condition or whether it could also be considered to refer to a physiological process. The Board underlined that the issue was important in particular in the context of the assessment of novelty over D2.

V. By letter of 1 May 2018 the respondent replaced the auxiliary request filed with the reply to the appeal with two auxiliary requests.

Claim 1 of auxiliary request 1 differed from claim 1 of the request considered by the opposition division to meet the requirements of the EPC in the deletion of the feature "and/or tooth wear" and in a minor editorial amendment.

Claim 1 of of auxiliary request 2 differed from claim 1 of auxiliary request 1 in the indication that the composition comprised a dispersing agent.

VI. Oral proceedings took place as scheduled on 8 May 2018.

VII. The arguments of the appellant, as far as they are relevant to the decision, can be summarised as follows:

(a) Main requests

Claim 1 could not be regarded as a purpose-limited product claim pursuant to Article 54(5) EPC since it encompassed also non-therapeutic treatments. There was no clear distinction in the patent between pathological conditions and physiological conditions. There was also no evidence that zinc oxide could effectively be used in the treatment of the conditions recited in the claim. Accordingly, claim 1 was anticipated by D1 and D2 that disclosed compositions containing zinc oxide in nano-particulate form.

(b) Auxiliary requests

Claim 1 of the auxiliary requests offended against Article 123(2) EPC since they were based on combinations of features that could not be derived clearly and unambiguously from the patent application as originally filed.

There was no evidence showing that zinc oxide could effectively be used in a method of helping to prevent, inhibit and/or treat dental erosion. Moreover, the use of the expression "helping" suggested that zinc oxide was not necessarily the active substance in treating the condition of claim 1. The data in the patent did not support the whole scope of the claims. Accordingly, auxiliary requests 1 and 2 did not comply with the requirement of sufficiency of disclosure. Furthermore, the compositions tested in the examples of the patent contained a dispersing agent. This was not reflected in the wording of claim 1 of auxiliary request 1.

D1 disclosed the use of zinc oxide in the treatment of demineralisation. The description of the patent-in-suit referred to the importance of treating demineralisation. D1 and the patent-in-suit related to the same type of treatment, namely a treatment for the remineralisation of teeth. Furthermore, compositions 8 and 9 of D1 did not contain palatinit, the absence of which was also required by claim 1. Thus D1 anticipated the subject-matter of the auxiliary requests.

Document D7 was the closest prior art for the assessment of inventive step. The subject-matter of the auxiliary requests differed from the disclosure of D7 in the requirement that zinc oxide was in nanoparticulate form. There was no evidence of any improvement arising from this distinguishing feature. This was true in particular for the compositions of auxiliary request 1 that did not necessarily contain a dispersing agent. The technical problem was to provide a suitable form of zinc oxide that was useful in the treatment of dental erosion. Several documents, in particular D1 and D2, disclosed compositions containing

zinc oxide in nanoparticulate form. Thus, claim 1 of the auxiliary requests did not involve an inventive step over D7 as the closest prior art in combination with e.g. D1 and D2.

VIII. The arguments of the respondent, as far as they are relevant to the decision, can be summarised as follows:

(a) Main requests

Tooth wear was not a physiological process. This was clear from the fact that not everyone suffered from it. Moreover, it was not a condition linked to the age of the patients and also children could suffer from this disease. Claim 1 was therefore to be assessed as a purpose-limited product claim. The claim was novel over D1 and D2.

(b) Auxiliary requests

Claim 1 of the auxiliary requests were based upon original claim 1 in combination with claim 3 (feature "nanoparticulate") and page 9 (feature "in the absence of palatinit"). Both auxiliary requests complied with the requirement of Article 123(2) EPC.

The patent contained several experimental examples demonstrating the efficacy of zinc oxide in nanoparticulate form in the treatment of dental erosion. The appellant did not submit any counter-evidence in this respect. Its objection with regard to the requirement of sufficiency of disclosure was not justified.

Document D1 related to the treatment of caries, a condition caused by plaque and involving a sub-surface

demineralisation. Dental erosion was a different condition involving the demineralisation of the enamel surface. Thus, D1 did not anticipate the subject-matter of claim 1 of the auxiliary requests.

Document D7 was the closest prior art for the assessment of inventive step. The subject-matter of the auxiliary requests differed from the disclosure of D7 in that zinc oxide was used in nanoparticulate form. The technical effect of the difference was the improvement of the anti-erosion effects. This effect was demonstrated in particular by the comparative data of example 7. The improved anti-erosion effect was not linked to the presence of a dispersing agent. The inclusion of a dispersing agent in the composition merely represented a preferred embodiment of the invention. There was no indication in the prior art that zinc oxide in nanoparticulate form provided improved anti-erosion effects. The subject-matter of the auxiliary requests complied therefore with the requirements of Article 56 EPC.

IX. The appellant requested that the decision under appeal be set aside and the patent be revoked.

X. The respondent requested that the appeal be dismissed and the patent thus be upheld as held allowable by the opposition division, or, in the alternative, that the patent be maintained on the basis of auxiliary request 1 or 2 filed with letter dated 1 May 2018.

Reasons for the Decision

Main request (request considered by the opposition division to meet the requirements of the EPC)

1. Novelty

1.1 Claim 1 is a purpose-limited product claim worded in accordance with Article 54(5) EPC. It relates to an oral care composition for use in a method of helping to prevent, inhibit and/or treat dental erosion and/or tooth wear.

1.2 The patent-in-suit does not provide any definition for the expression "tooth wear". In paragraph [0006], it is stated that tooth wear is caused by attrition and/or abrasion. The same paragraph explains that an example of attrition can be observed in subjects affected by bruxism whereas abrasion typically occurs as a result of three-body wear and the most common example is that associated with brushing with a toothpaste.

1.3 None of the prior art documents considered in these proceedings refers to a medical condition designated as "tooth wear". Nor has the respondent submitted any piece of evidence that could demonstrate that "tooth wear" is a recognised definition for a pathological condition or a class of pathological conditions.

1.4 It follows from the above that the meaning of the expression "tooth wear" has to be construed on the basis of the small amount of information disclosed in the patent and in particular in paragraph [0006]. The indication that tooth wear can be caused by attrition and abrasion and that it can be associated with tooth brushing means in the Board's view that this expression

has been used in the patent as a generic definition that covers also physiological conditions. In other words the expression "tooth wear", considered in the light of the whole teaching of the patent, although it includes pathological conditions (e.g. bruxism) it does not exclude for instance a "physiological" tooth degradation caused by ageing.

1.5 Article 54(5) EPC provides for notional novelty of a known substance or composition for any specific use (second or further use) in a method of treatment of the human or animal body by therapy, provided that such use is not comprised in the state of the art.

It follows from the considerations set out in point 1.4 above, that the treatment of tooth wear, as this expression can be construed in the context of the patent, is not necessarily linked to the treatment of a pathological condition or a disorder or malfunction of the human or animal body. In the Board's view, such a treatment does not qualify as a method of treatment by therapy.

Accordingly, the provisions of Article 54(5) EPC for the assessment of novelty do not apply to present claim 1. Thus, the indication in this claim that the oral care compositions are for use in a method of helping to treat tooth wear merely means that the oral care compositions are suitable for that use.

1.6 Document D2 describes compositions that contain zinc oxide in the form of nanoparticles and do not contain palatinit (see example 2 to 5). These compositions are useful to prevent the formation of plaque. The Board sees no reasons why these compositions should not be

suitable also in the treatment of tooth wear. The respondent did not submit any argument in this respect.

1.7 The Board therefore concludes that the subject-matter of claim 1 is not novel over D2.

Auxiliary request 1

2. Article 123(2) EPC

2.1 Claim 1 of the original application reads as follows:

"An oral care composition for combating dental erosion and/or tooth wear comprising particulate zinc oxide".

2.2 The expression "for combating" has been replaced in claim 1 of auxiliary request 1 by the feature "for use in a method of helping to prevent, inhibit, and/or treat". This amendment has a clear support on page 1 (lines 7 and 8) of the original application.

Claim 1 of auxiliary request 1 specifies that zinc oxide is in nanoparticle form and that the composition does not contain palatinit. These features are based respectively on page 8 (line 8) and page 9 (line 19 and 20) of the original application. These passages of the description relate in general to all the compositions disclosed in the application and therefore also to the compositions defined in original claim 1. Thus, the introduction in the context of original claim 1 of the features concerning the particulate form of the zinc oxide and the absence of palatinate does not involve any addition of subject-matter.

Finally, "dental erosion" is a medical condition disclosed in original claim 1.

Accordingly, claim 1 of auxiliary request 1 meets the requirements of Article 123(2) EPC.

2.3 The appellant did not raise any further objections under Article 123(2) EPC against the remaining claims of auxiliary request 1. The Board is satisfied that this request meets the requirements of Article 123(2) EPC.

3. Sufficiency of disclosure

3.1 Claim 1 is drafted as a purpose-limited product claim pursuant to Article 54(5) EPC. In order to assess the requirement of sufficiency of disclosure it needs to be verified whether the description discloses the potential suitability of the composition defined in claim 1 for the therapeutic application recited in the claim, namely the treatment of dental erosion.

3.2 In this regard it is noted that the description discloses several examples in support of the activity as anti-erosion agents of compositions containing zinc oxide in nanoparticulate form. Example 3 for instance, shows that compositions containing 0.50% of zinc oxide in nanoparticulate form provide better protection against acid exposure than control compositions that do not contain zinc oxide. The inventive compositions tested in example 3 do not contain any dispersing agent. Similar conclusions can be drawn from examples 4 and 5. In these cases the compositions of the invention contain, in addition to zinc oxide in nanoparticulate form, also a dispersing agent. The examples also show that compositions containing only zinc oxide in nanoparticulate form are less active than compositions containing fluoride ions or than compositions

containing a combination of fluoride ions and zinc oxide (which are also covered by claim 1). However, this observation does not imply that zinc oxide alone is not active in the treatment of the conditions defined in claim 1.

3.3 The appellant argues that claim 1 does not include any indication as to e.g. the amount of zinc oxide to be used in the treatment, the presence of other substances in the composition or the dosage regime.

In this regard the Board agrees with the respondent that the skilled person would in principle be able to optimise these parameters in order to prepare compositions which are effective in the treatment of dental erosion. Furthermore, the examples disclosed in the patent would provide some guidance in this respect.

3.4 As a further argument, the appellant submits that the term "helping" in claim 1 is ambiguous and that the skilled person would not know what is required of a composition to "help" in preventing or treating dental erosion.

The Board considers that this issue relates to a potential problem of clarity rather than sufficiency of disclosure. However, since the expression "helping to prevent, inhibit and/or treat" was already included in claim 1 as granted, no objection under Article 84 EPC can be raised in this respect, in line with G 3/14 (OJ EPO 2015, A102).

In any case, the skilled person would understand, for instance form paragraph [0001] of the description, that "helping to prevent, inhibit, and or treat...", simply means that the compositions of the patent are active in

the prevention, inhibition or treatment of the condition defined in claim 1. Thus, the use of the term "helping" does not affect the possibility of carrying out the invention defined in claim 1.

3.5 Accordingly, auxiliary request 1 meets the requirements of sufficiency of disclosure.

4. Novelty

4.1 The appellant's objection against the novelty of the subject-matter of auxiliary request 1 is based on the disclosure of document D1.

4.2 In the description of the patent-in-suit a distinction is made between caries and dental erosion (paragraphs [0003] to [0005]). It is explained that the presence of acidogenic bacteria and the formation of plaque are prerequisites for dental caries development whereas they are not involved in dental erosion. The Board notes that also in D4 (page 1, lines 8 to 19) and D7 (paragraph bridging pages 1 and 2) a clear distinction is made between caries and dental erosion.

4.3 There is no reference in D1 to the treatment of dental erosion. The compositions disclosed in this document are used to enhance the remineralisation in the context of caries treatment (column 1, lines 18 to 21). Indeed, the evaluation of the remineralising ability of the compositions of D1 discussed in experimental examples 2 and 3 is based on an *in vitro* test that simulates caries (column 4, lines 35 to 48).

Hence, the subject-matter of claim 1 of auxiliary request 1 is novel over D1 alone for the reason that

this document does not disclose any method of treating dental erosion.

4.4 During the oral proceedings before the Board a thorough discussion took place on the role of remineralisation in the treatment of caries and of dental erosion. In the appellant's opinion the treatment of both conditions requires the remineralization of the teeth.

This matter is in the Board's view of no relevance for the assessment of novelty over D1. Even assuming, in the appellant' s favour, that zinc oxide acts as a remineralising agent both in the treatment of caries and in the treatment of dental erosion, this does not affect the conclusion that caries and dental erosion are two different medical conditions (see point 4.2 above). This was not contested by the parties, and is a sufficient reason to conclude that claim 1 is not anticipated by D1.

5. Inventive step

5.1 Closest prior art

5.1.1 Document D7 relates to a method of treating and protecting teeth against erosion (page 1, line 1 and last paragraph of page 2). The Board agrees with the opposition division that this document represents the closest prior art.

5.1.2 D7 indicates that compounds which are source of metal ions, such as zinc oxide, produce insoluble deposits on tooth surface and provide surface protection effects (page 8, lines 12 to 16 and page 9, line 11). The compositions disclosed in D7 contain, in addition to a source of metal ions, also a "polymeric mineral

surface-active agent" (see paragraph bridging pages 4 and 5).

The subject-matter of auxiliary request 1 differs from the disclosure of D7 in the requirement that zinc oxide is used in nanoparticulate form.

5.2 Technical problem

5.2.1 In the respondent's view, the use of zinc oxide in nanoparticulate form results in an improvement of the anti-erosion effects. In its opinion, this improvement would be demonstrated by example 7 of the patent-in-suit which describes an experiment relating to the assessment of the anti-erosion properties of several compositions.

5.2.2 The relevant data of example 7 are those relating to the following compositions:

(a) "nano ZnO": containing 0.5% of Nanoshiled ZN-3008C, i.e. zinc oxide in nanoparticulate form stabilised with anionic dispersant (see also example 4), and

(b) "ZnO": containing 0.5% of bulk zinc oxide.

Graph 5 (paragraph [0085]) shows that the composition "nano ZnO" is more effective in preventing demineralisation than composition "ZnO".

The same tendency is shown by compositions which contain in addition to the zinc compounds also 225 ppm of fluoride (Graph 6).

5.2.3 As remarked by the appellant, the composition "nano ZnO" differs from the composition "ZnO" not only on

account of the particle size of the zinc oxide but also in the presence of an anionic dispersant. Thus, the Board considers that example 7 is no evidence of an improvement arising from the distinguishing feature over D7, i.e. from the particle size of the zinc oxide. In other words, example 7 does not demonstrate that using zinc oxide in nanoparticulate form instead of standard zinc oxide necessarily results in an improvement of the anti-erosion properties of the composition since it cannot be ruled out that the anionic dispersant included in the "nano ZnO" composition has an impact on the behaviour of the composition.

The respondent's argument that the presence of a dispersing agent merely represents a preferred embodiment of the invention, suggests, in the Board's view, that compositions containing a dispersing agent may have better properties than compositions not containing it but still covered by claim 1. However, a technical effect can be taken into account for the formulation of the technical problem only when it is achieved throughout the entire scope of a claim. An evidence of a technical effect achieved by the preferred embodiment of a claim does not allow to conclude that the remaining embodiments covered by the claim would also achieve this effect.

5.2.4 Hence, in the Board's view there is no evidence that the compositions of claim 1 are more effective than the compositions of D7 in the treatment and prevention of dental erosion.

The technical problem is therefore to be seen in the provision of an alternative oral care composition for the treatment of dental erosion.

5.3 Obviousness

5.3.1 Document D7 does not provide any restriction as to the particle size of the zinc oxide. Dental care compositions containing zinc oxide in nanoparticulate form are disclosed for instance in document D2 (see examples 2 to 5).

Thus, the skilled person confronted with the mere problem of providing an alternative to the compositions of D7 would consider the replacement of zinc oxide with another suitable form of this substance, such as the zinc oxide in nanoparticulate form disclosed in D2. In this way he would arrive at the claimed subject-matter without exercising any inventive skill.

It follows that auxiliary request 1 does not fulfil the requirements of Article 56 EPC.

Auxiliary request 2

6. Article 123(2) EPC

6.1 Claim 1 of this request differs from claim 1 of auxiliary request 1 in the requirement that the oral care composition comprises a dispersing agent.

This feature is disclosed in claim 5 of the application as originally filed which refers back to all the preceding claims.

Thus, claim 1 meets the requirements of Article 123(2) EPC.

7. Sufficiency of disclosure and novelty

7.1 The considerations set out in points 3 and 4 above in relation to the subject-matter of auxiliary request 1 apply also to the subject-matter of auxiliary request 2. It follows that this request fulfils the requirements of sufficiency of disclosure and novelty.

8. Inventive step

8.1 The composition of claim 1 differs from the compositions disclosed in D7 in the requirement that zinc oxide is used in nanoparticulate form and in the presence of a dispersing agent.

8.2 As discussed in point 5.2.2 above, example 7 shows that a composition containing zinc oxide in nanoparticulate form stabilised with anionic dispersant (composition "nano ZnO") is more effective in preventing demineralisation than a composition containing bulk zinc oxide (composition "ZnO").

The Board agrees with the respondent and with the oppositions division that the skilled person would understand that the expression "bulk zinc oxide" used in example 7 of the patent identifies the standard grade of the material that has not been micronised. Thus, the product "nano ZnO" differs from the product "ZnO" in the particle size of the zinc oxide and in the presence of a dispersing agent, i.e. in the features that distinguish the subject-matter of claim 1 over D7.

8.3 In the light of the experiments disclosed in example 7 the technical problem can be formulated as the provision of an oral care composition which is more effective in the treatment of dental erosion.

8.4 Neither D7 nor any other cited document relied upon by the appellant suggests to solve this problem by the provision of a composition comprising zinc oxide in nanoparticulate form and a dispersing agent.

Therefore, auxiliary request 2 meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of auxiliary request 2 and a description to be adapted thereto.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated