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Datasheet for the decision of 6 November 2018

Case Number: T 0038/16 - 3.3.07

Application Number: 10173204.8

Publication Number: 2289482

A61K6/00, A61K8/19, A61K8/24, IPC:

A61K8/81, A61Q11/00

Language of the proceedings: ΕN

Title of invention:

Method of protecting teeth against erosion

Patent Proprietor:

The Procter & Gamble Company

Opponents:

Glaxo Group Limited Colgate-Palmolive Company Henkel AG & Co. KGaA

Headword:

Method of protecting teeth against erosion/The Procter & Gamble Company

Relevant legal provisions:

EPC Art. 76(1), 123(2)

Keyword:

Main request - Amendments (Yes)

Decisions cited:

Catchword:



Representative:

Beschwerdekammern **Boards of Appeal** Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar **GERMANY**

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Case Number: T 0038/16 - 3.3.07

DECISION Technical Board of Appeal 3.3.07 of 6 November 2018

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 29 October 2015 revoking European patent No. 2289482 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
C. Schmidt

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Summary of Facts and Submissions

I. European patent No. 2 289 482 is based upon European patent application 10 173 204.8. In the following EP 2 289 482 B1 is called the "present patent" whereas the application No 10 173 204.8 or the corresponding publication EP 2 289 482 A2 are called the "present application". The present patent was granted on the basis of a set of 2 claims.

Independent claim 1 as granted read as follows:

- "1. A dentifrice composition comprising a) a polymeric mineral surface-active agent selected from polyphosphonates; polycarboxylates and carboxysubstituted polymers; copolymers of phosphate- or phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, or with other polymers selected from proteins, polypeptides, polysaccharides, poly(acrylate), poly(acrylamide), poly(methacrylate), poly(ethacrylate), poly(hydroxyalkylmethacrylate), poly(vinyl alcohol), poly(maleic anhydride), poly(maleate) poly(amide), poly(ethylene amine), poly(ethylene glycol), poly(propylene glycol), poly(vinyl acetate) or poly(vinyl benzyl chloride); and mixtures thereof, wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage; and
- b) an effective amount of a source of metal ions selected from the group consisting of stannous, zinc, copper, and mixtures thereof for use in protecting a subject's teeth against dental erosion following use of the composition."

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- II. Three oppositions were filed against the granted patent under Article 100(a), (b) and (c) EPC 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.
- III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on 4 sets of claims, namely the claims as granted as main request, auxiliary request 1 filed during the oral proceedings on 1 October 2015, auxiliary request 2 filed with letter dated 1 September 2015 and auxiliary request 3 filed during the oral proceedings on 1 October 2015.
- The documents cited during the opposition proceedings included the following:
 D26: PAT's letter in opposition against parent application EP 1569609
 D27: Preliminary opinion of the OD in relation with opposition against parent application EP 1 569 609
 - opposition against parent application EP 1 569 609 D28: Interlocutory decision of July 2015 in parent application EP 1 569 609
- V. According to the decision under appeal, D26-D28 were not admitted into the proceedings under Rule 116 EPC, since they were prima facie not relevant.

 The opposition division was of the opinion that claim 1 of the main request contravened Article 76(1) EPC since said claim failed to disclose that the protection last for "extended periods of time" or last "immediately after use of the oral composition and for a period of at least about one hour or longer thereafter".

Claim 1 of the main request contravened also Article 123(2) EPC, the feature "substantive to teeth and

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deposits and layer" was linked with a protection "immediately after use" and not "following use".

Auxiliary request 1 was not admitted since it did not prima facie meet the requirements of Articles 84 and 123(2) EPC.

Claim 1 of auxiliary request 2 failed to disclose that the metal ions (b) were in the form of an insoluble film or precipitate of compounds or complexes, and thus auxiliary request 2 did not meet the requirements of Article 123(2) EPC.

Auxiliary request 3 was not admitted since it did not prima facie meet the requirements of Article and 123(2) EPC.

- VI. The proprietor (hereinafter the appellant) filed an appeal against that decision. With the statement of grounds of appeal dated 8 March 2016, the appellant filed 2 auxiliary requests.
- VII. With a letter dated 26 July 2016, opponent 02 (hereinafter respondent 02) requested that the appeal be dismissed and that D28 and auxiliary request 2 not be admitted into the proceedings.
- VIII. In a communication dated 14 September 2018 sent in preparation of oral proceedings, the Board gave its preliminary opinion. In particular, it stated that the main request met the requirements of Articles 76(1) and 123(2) EPC.
- IX. Oral proceedings took place on 6 November 2018.

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X. The arguments of the appellant may be summarised as follows:

Main request - Articles 123(2) and 76(1) EPC

Amendments in claim 1 going from the international parent application as filed (see W02004054529 A1) to the present application as filed were:

- changing a medical treatment claim to a second medical use claim;
- limiting the list of polymers by deleting the first entry;
- deleting the functional feature from the claim that the composition is substantive to teeth; and
- amending the medical indication so that protection from erosion is "following use".

Amendments going from the present application as filed to the granted claims of the present patent were:

- reintroducing the functional feature, in part;
- addition of metal ions; and
- limiting the oral care composition to a dentifrice.

Deleting one entry from a list of some length was shortening the list, not making a selection from the list and hence was an acceptable amendment to make.

A basis for the functional feature of substantivity to teeth, without limitation to the precise duration, was to be found at page 3, first paragraph of both the international parent application and the present application EP 10 173 204.8 as filed.

The metal ions had a basis in claim 5 of the international parent application as filed and claim 3 of the present application as filed.

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A dentifrice was disclosed at page 16, final paragraph of the international parent application as published. It was also singled out for discussion at page 4, and is the subject-matter of the examples. It was therefore clearly preferred and hence no selection was required to identify it as preferred. Similar disclosures were to be found in the present application as filed.

The polymeric mineral surface-active agent had been limited such that it is "substantive to teeth and deposits a layer that protects teeth from erosive damage". Basis for this amendment could be found at least at page 3, lines 10-12 of the present application EP 10 173 204.8 as filed.

A basis could be found for the term "following use" on page 3 of the description of the parent and present patent application EP 10 173 204.8.

Claim 1 as granted had basis in the parent and the application as filed and hence the requirements of Articles 76(1) and 123(2) EPC were met.

XI. The arguments of the respondents may be summarised as follows

Main request - Article 76(1) EPC

According to respondent 01, claim 1 of the Main Request recited a specific feature combination of (i) a dentifrice; (ii) a polymeric mineral surface activeagent (of a particular composition); (iii) the functional technical feature that the polymeric mineral surface active-agent is substantive to teeth and deposits a layer that protects teeth from erosive

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damage; (iv) a source of metal ions (of a particular composition); and (v) the functional technical feature that the dentifrice composition is for use in protecting a subject's teeth against dental erosion challenges following use of the composition. The combination of said features was not derivable from the parent application.

There was no objective disclosure in the parent application (see W02004054529 A1) that when the composition comprised both (ii) a polymeric mineral surface active-agent (of a particular composition); and (iv) a source of metal ions that the teeth are protected for any indeterminate period of time at any point in time after use. Claim 7 of the parent application specifically disclosed a composition including metal ions, and required the time period discussed above. The omission of the feature that, when the metal ions were present, protection was provided immediately after use of the composition and maintained for prolonged periods of time for at least about one hour thereafter, constituted an undisclosed intermediate generalisation contravening Article 76(1) EPC.

There was no objective disclosure in the parent application of the combination of a polymeric mineral surface-active agent which was substantive to teeth and deposited a layer that protects teeth from erosive damage in combination with a source of metal ions which did not deposit onto teeth a highly insoluble film or precipitate, and in particular in an arbitrarily selected dentifrice.

The term "dental erosion challenge" was used in the parent application in each case in a specific test or

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regime, for example exposing the teeth to an acid such as Coca Cola. The disclosure in claim 1 of the main request of the dental erosion challenges but arbitrarily omitting the feature that the layer had a particular composition, particularly when the metal ions are present, and that protection is provided for specific times, constituted an undisclosed intermediate generalisation contravening Article 76(1) EPC.

According to respondent 02, the feature "for protecting a subject's teeth against dental erosion challenges following use of the composition" represented subject matter extending beyond the content of the parent application as filed, contrary to Article 76(1) EPC. Page 1, penultimate paragraph of the parent application as filed stated: "As a result of these protective coatings, teeth are provided with remarkable resistance and protection against dental erosion challenges for extended periods of time following use of the composition containing these agents." There was no reference in claim 1 to "extended periods of time", as was recited in this passage. The removal of this feature resulted in a broadening with respect to the content of the application as originally filed. Moreover, the term "following use" was always associated with a time sequence in the description on pages 1, 2, 3, 5 or 8. There was a consistent disclosure of time element which was not in claim 1.

According to respondent 02, the deletion of a polymer in the claimed list was also seen as a selection which could not be combined with the other features.

Main request - Article 123(2) EPC

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According to respondent 01, granted claim 1 disclosed a new combination of features, and so contravenes Article 123(2) EPC:

- The combination of claims 1 and 3 of the present patent application did not disclose the feature (iii) that "said polymeric mineral surface active-agent is substantive to teeth and deposits a layer that protects teeth from erosive damage. The claims of the present patent application did not disclose depositing a layer, and in particular do not disclose what layer is deposited when the composition comprises both (ii) a polymeric mineral surface active-agent (of a particular composition); and (iv) a source of metal ions. There were three disclosures in the description of the present patent application which disclosed the deposition of a layer when a composition comprising both (ii) a polymeric mineral surface active-agent (of a particular composition); and (iv) a source of metal ions (of a particular composition) is used. However, arbitrarily omitting the feature of the insoluble film or precipitate, formed from the metal ions, constituted an undisclosed intermediate generalisation contravening Article 123(2) EPC.
- There was no objective disclosure in the present patent application of depositing a layer that protected teeth against dental erosion challenges, or that such a layer might have had any composition, or that the protection against dental erosion is for any indeterminate time period. The omission in claim 1 of the main request that the layer had a particular composition, particularly when the metal ions are present, and that protection was provided for specific times, constituted an undisclosed intermediate generalisation contravening Article 123(2) EPC.

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According to respondent 02, the deletion of a polymer in the claimed list was seen as a selection and not a shortening of the list. It was not possible to make a distinction between "selection" and "shortening". Both "shortening" and "selection" involved the deletion of alternatives. The change starting from the originally disclosed list of polymers to arrive at the list of polymers according to claim 1 as granted could be described accurately as the deletion of an alternative from a list.

Moreover, the feature "wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage" was present in the first sentence on page 3, but this was in connection with the feature "a method of protecting a subject's teeth from erosion caused by the action of chemicals" (see EP 10 173 204.8, page 3, lines 1 and 2). The omission of the reference to the erosion being caused by the action of chemicals from claim 1 represented an impermissible generalization from the content of the application as originally filed.

The introduction of the feature wherein the composition is a "dentifrice" involved also a selection. Making a first deletion from the list of polymers and a second deletion from the list of types of oral composition so as to arrive at the combination of features recited in claim 1 added subject matter because it involved deletion from two lists, thereby creating new combinations of features.

XII. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained according the claims as granted or alternatively - 10 - T 0038/16

according to auxiliary requests 1 or 2, both filed with letter dated 8 March 2016. The appellant also requested that the case be remitted to the Opposition Division for considering the remaining grounds of opposition.

Respondents 1 and 2 requested that the appeal be dismissed.

Respondent 2 also requested that auxiliary request 2 and document D28 not be admitted into the proceedings.

Respondent 3 did not submit any request.

Reasons for the Decision

- 1. Main request Article 76(1) EPC
- 1.1 Claim 1 of the parent application WO 2004/054529 reads the following:
 - "1. A method of protecting a subject's teeth from erosion comprising administering to the subject's oral cavity an oral care composition comprising a polymeric mineral surface-active agent selected from the group consisting of condensed'phosphorylated polymers; polyphosphonates; polycarboxylates and carboxysubstituted polymers; copolymers of phosphate-or phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, or with other polymers selected from proteins, polypeptides, polysaccharides, poly (acrylate), poly (acrylamide), poly (methacrylate), poly (ethacrylate), poly (hydroxyalkylmethacrylate), poly (vinyl alcohol), poly (maleic anhydride), poly (maleate) poly (amide), poly (ethylene amine), poly (ethylene glycol), poly (propylene glycol), poly (vinyl acetate) or poly (vinyl benzyl chloride); and mixtures thereof, wherein said

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polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage immediately after use of the oral composition and for a period of at least about one hour or longer thereafter."

The description of the parent application discloses also on page 3, lines 1-12 the following: "The present invention relates to a method of protecting a subject's teeth from erosion caused by the action of chemicals, such as harsh abrasives and acids, by the use of an oral care composition comprising a polymeric mineral surface-active agent selected from the group consisting of condensed phosphorylated polymers; polyphosphonates; polycarboxylates and carboxy-substituted polymers; copolymers of phosphateor phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, or with other polymers selected from proteins, polypeptides, polysaccharides, poly (acrylate), poly (acrylamide), poly (methacrylate), poly (ethacrylate), poly (hydroxyalkylmethacrylate), poly (vinyl alcohol), poly (maleic anhydride), poly (maleate) poly (amide), poly (ethylene amine), poly (ethylene glycol), poly (propylene glycol), poly (vinyl acetate) or poly (vinyl benzyl chloride); and mixtures thereof, wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage.".

The description on page 3, lines 12-14 discloses further:

"Advantageously, the antierosion protection is provided immediately after use of the present compositions and maintained for prolonged periods of time for at least about one hour thereafter."

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- 1.2 Claim 1 as granted differs from claim 1 or from the description, page 3, lines 1-12 of the parent application in following points:
 - i) reformulation in a product claim
 - ii) addition of the feature "a dentifrice composition"
 iii) the deletion of "condensed phosphorylated
 polymers" in the list of polymeric mineral surfaceactive agent
 - iv) the addition of feature "b) an effective amount of a source of metal ions selected from...and mixtures thereof".
 - v) the addition of the feature "for use in protecting a subject's teeth against dental erosion challenges following use of the composition".
 - vi) the suppression of the feature "immediately after use of the oral composition and for a period of at least about one hour or longer thereafter"

1.2.1 Point i)

Claim 1 of the parent application refers directly and unambiguously to an oral care composition. There is therefore a direct basis in claim 1 of the parent application for a product claim. Such a basis is also to be found in the description of the parent application on page 3, lines 1-12.

1.2.2 Point ii)

The feature "a dentifrice composition" finds a basis on page 4, first paragraph, of the description of the parent application which reads "the oral composition of the present invention may be in the form of a toothpaste, dentifrice, tooth powder, topical oral gel, mouthrinse, denture product, mouthspray, lozenge, oral

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tablet, or chewing gum". The cited passage further specifies what is meant by "dentifrice" (see page 4, second paragraph), and all examples of the parent application disclose dentifrice compositions. It is thus immediately apparent from said disclosure that the "dentifrice compositions" are the preferred embodiment of the invention. A restriction to a "dentifrice composition" is thus derivable directly and unambiguously from the parent application.

1.2.3 Point iii)

As regards point iii) the deletion of one element in a list comprising more than twenty elements, namely the deletion of the feature "condensed phosphorylated polymers" in the list of polymeric mineral surface—active agents, is seen as a restriction in a disclosed list, and not as a selection. The disclosure of the list of polymeric mineral surface—active agents is therefore derivable directly and unambiguously from the originally disclosed list.

1.2.4 Point iv)

A basis for the feature "b) an effective amount of a source of metal ions selected from...and mixtures thereof" is also to be found in the parent application. The addition of feature "b) an effective amount of a source of metal ions selected from...and mixtures thereof" finds indeed an explicit basis in dependent claim 5 of the parent application which discloses that the oral care composition "further comprises an effective amount of a source of metal ions selected from the group consisting of stannous, zinc, copper, and mixtures thereof" or in the description on page 8, lines 17-18, which discloses that "the present"

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compositions may comprise a metal ion source that provides stannous ions, zinc ions, copper ions, or mixtures thereof".

1.2.5 Point v)

Point v) relates to a medical indication, namely "for use in protecting a subject's teeth against dental erosion challenges following use of the composition". The treatment of dental erosion challenges is disclosed in a repetitive way in the description of the parent application. As mentioned by respondent 02, said disclosure is associated with a time restriction on pages 1, 3 and 8 of the description of the parent application. It is however apparent that the "use in protecting a subject's teeth against dental erosion challenge" stems directly from the expression "protecting a subject's teeth from erosion caused by the action of chemicals", found on page 3, line 1-2. The addition of the word "challenges", which was used in multiple parts of the description as noted by respondent 02, does not change the meaning of the disclosure of page 3, lines 1-2.

As to the presence of the term "following use", this term is simply considered as a synonym of the term "by the use" disclosed on page 3, line 2. Hence, there is no need to consider the further passages mentioned by respondent 02 as a potential basis comprising also a linked time element (passages cited on pages 2, 3 4, 5). As a general rule, when assessing Article 76(1) or 123(2) EPC, it is indeed sufficient to indicate the basis for an amendment, and not to discuss passages where it might not be disclosed directly and unambiguously. Moreover, the introduction of this term cannot be seen as a restriction, since it is

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immediately obvious to a skilled person, that the dentifrice composition will protect the subject's teeth after its use, thus "by the use" or "following use" thereof.

1.2.6 Point vi)

A basis for a composition with the suppression of the feature "immediately after use of the oral composition and for a period of at least about one hour or longer thereafter" finds also a direct basis in the disclosure of the composition on page 3, lines 1-12 which does not comprise any restriction as to the delay or length of action. This disclosure of the description is directly transposable to the subject-matter of claim 1 of the parent application, which generalized object is derivable directly and unambiguously from the cited passage of the description.

1.2.7 The respondent's argument that the subject-matter of claim 1 is a new combination of features could also not be followed by the Board. A restriction by amendments based on preferred embodiments, as it is obvious for points i)-v) as discussed above, cannot be seen as a combination of features which is not derivable directly and unambiguously from the parent application.

All amendments originate from preferred embodiments from the description or from dependent claims of the parent application and constitute preferred embodiments relating to the claimed composition. Their incorporation in claim 1 constitutes therefore a restriction to specific preferred embodiments and under no circumstances a restriction to a combination of alternative embodiments or an individualisation to a

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subject-matter not specifically disclosed in the parent application.

1.3 Hence, the subject-matter of claim 1 of the main request is derivable directly and unambiguously from the parent application and the main request meets the requirements of Article 76(1) EPC.

2. Main request - Article 123(2) EPC

- 2.1 Claim 1 of the present patent application
 (EP 10 173 204.8 or EP 2 289 482 A2) reads as
 following:
 - "1. The use of an oral care composition comprising a polymeric mineral surface-active agent selected from the group consisting of polyphosphonates; polycarboxylates and carboxy-substituted polymers; copolymers of phosphate- or phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, or with other polymers selected from proteins, polypeptides, polysaccharides, poly(acrylate), poly(acrylamide), poly(methacrylate), poly(ethacrylate), poly(hydroxyalkylmethacrylate), poly(vinyl alcohol), poly(maleic anhydride), poly(maleate) poly(amide), poly(ethylene amine), poly(ethylene glycol), poly(propylene glycol), poly(vinyl acetate) or poly(vinyl benzyl chloride); and mixtures thereof, for protecting a subject's teeth against dental erosion challenges following use of the composition."
- 2.2 Claim 1 as granted differs from claim 1 of the present patent application in following points:
 - i) reformulation in a product claim
 - ii) addition of the feature "a dentifrice composition"

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- iii) the deletion of "condensed phosphorylated
 polymers" in the list of polymeric mineral surfaceactive agent
- iv) the addition of the feature "wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage"
- v) the addition of feature "b) an effective amount of a source of metal ions selected from...and mixtures thereof".
- 2.2.1 The conclusions reached above for Article 76(1) EPC apply also to Article 123(2) EPC, as regards points i)-iii), the description of the present patent application (see EP 10 173 204.8) being identical to the description of the parent application (see WO 2004/054529).

The basis for point i) is to be found directly in claim 1 of the present patent application.

As to point ii), the "dentifrice composition", it can be found in page 3, line 31 to page 4, line 11 of EP 10 173 204.8 (corresponding to paragraphs [0012]-[0013] of EP 2 289 482 A2) and in the examples of the present patent application; this passage corresponds to the passage mentioned above for the parent application, on page 3 last paragraph and page 4, first and second paragraph. As for the reasoning held under Article 76(1) EPC above, a restriction to a "dentifrice composition" is derivable directly and unambiguously from the parent application.

As regards point iii), the disclosure of the list of polymeric mineral surface-active agents with the deletion of one element in a list comprising more than

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twenty elements, namely the deletion of the feature "condensed phosphorylated polymers" in the list of polymeric mineral surface-active agents, derivable directly and unambiguously from the originally disclosed list.

- 2.2.2 Point iv) finds a direct disclosure in the description of the present patent application on page 3, lines 1-12 of EP 10 173 204.8 (corresponding to in paragraph [0007] of EP 2 289 482 A2). This passage corresponds to the passage mentioned above for the parent application, on page 3, lines 1-12, and relates to the same composition. Feature iv) is therefore directly transposable to the subject-matter of claim 1.
- 2.2.3 Point v) finds a direct basis in dependent claim 3 of the present patent application.
- 2.3 Hence, the subject-matter of claim 1 of the main request is derivable directly and unambiguously from the present patent application and the main request meets the requirements of Article 123(2) EPC.
- 3. Remittal to the opposition division

Although Article 111(1) EPC does not guarantee a party an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should, whenever possible, be given the opportunity to said consideration by two instances of the important elements of the case. The essential function of an appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted if further criteria of patentability have not yet been examined and decided by the

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department of first instance. This is the situation here.

Hence, the Board considers it appropriate to remit the case to the opposition division for further prosecution on the basis of the main request.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated