

Publication in the Official Journal Yes / No

File Number: T 290/86 - 3.3.1
Application No.: 78 300 055.7
Publication No.: 0 000 256
Title of invention: Method of cleaning teeth and composition for use
in such method

Classification: A61K 7/16

D E C I S I O N
of 13 November 1990

Proprietor of the patent: Imperial Chemical Industries PLC

Opponent: Blendax GmbH

Headword: Cleaning plaque/ICI

EPC Articles 52, 54 and 56

Keyword: "Therapeutic method (yes)" - "Novelty of composition claims
with disclaimers of examples (no)" - "Second medical
indication novel and inventive"

Headnote

I. Whether or not a claimed invention is excluded from patentability under Article 52(4) EPC depends in particular upon the wording of the claim in question. If the claimed invention is not directed solely to a cosmetic effect, but is also necessarily defining a treatment of the human body by therapy as well, such a claim is excluded from patentability (Decision T 144/83 "Appetite suppressant (OJ EPO 1986, 301) distinguished).

II. What is "made available to the public" by specific detailed examples included in a document is not necessarily limited to the exact details of such specific examples but depends in each case upon the technical teaching which is "made available" to a skilled reader. The amendment of a claim by including a disclaimer to such specific detailed examples may not render the claim novel.

III. When a prior document and a claimed invention are both concerned with a similar treatment of the human body for the same therapeutic purpose (here: prevention of tooth decay), the claimed invention represents a further medical indication as compared to the prior document within the meaning of Decision G 5/83 (OJ EPO 1985, 64) if it is based upon a different technical effect which is both new and inventive over the disclosure of the prior document (here: use of compositions including lanthanum salts to reduce the solubility of tooth enamel cf. use of such compositions to improve the removal of plaque from teeth).



Case Number : T 290/86 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 13 November 1990

Appellant :
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Representative :

Decision under appeal : Decision of Opposition Division of the European Patent Office dated 23 April 1986, posted on 1 July 1986 revoking European patent No. 0 000 256 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : K.J.A. Jahn
Members : R.W. Andrews
G.D. Paterson

Summary of Facts and Submissions

I. European patent No. 0 000 256 in respect of European patent application No. 78 300 055.7, which was filed on 20 June 1978, was granted on 13 April 1983 (cf. Bulletin 83/15) on the basis of four claims, independent Claims 1 and 3 reading as follows:

"1. A method of cleaning plaque and/or stains from human teeth by applying thereto, as the sole oral hygiene agent, a non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water-soluble salt, said composition being free from any ingredients which precipitate the cation as a water-insoluble salt.

3. A non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water soluble salt, said composition being free from any ingredients which precipitate the cation as a water-insoluble salt, and being a mouthwash, oral spray, toothpaste or dental gel."

II. On 21 July 1983 a notice of opposition was filed requesting the revocation of the patent on the grounds set forth in Article 100(a) and (c) EPC. The opposition was supported, *inter alia*, by the following documents:

- (1) GB-A-654 472
- (3) Journal of Dental Research Vol. 28, No. 2 (1949), 160-171.

The patent specification (document (1)) is dated 1948, and discloses the use of dentifrice preparations containing salts of an element from a defined group to depress the solubility of tooth enamel in organic acids, and thus to

inhibit tooth decay. Lanthanum is one of many elements within the defined group. None of the specific examples in this patent discloses the use of lanthanum. Nevertheless, lanthanum is specifically mentioned in a subsidiary claim as being the element present in the claimed preparation.

During the proceedings before the Opposition Division, amended method and composition claims were filed by the patentee, by way of main and auxiliary requests.

- III. By a decision delivered orally on 23 April 1986, with written reasons posted on 1 July 1986, the Opposition Division revoked the patent. The Opposition Division held that the method claims of the main and auxiliary requests covered both a cosmetic and curative effect. Since methods for treatment of the human body by therapy are not regarded as inventions which are susceptible of industrial application within the meaning of Article 52(1) EPC, the patent was revoked on this ground.

Furthermore, the Opposition Division held that the subject-matter of all of the composition claims of the main and auxiliary requests lacked novelty in the light of the disclosure of document (1), on the basis that document (1) discloses a dental preparation containing a lanthanum salt, and that the mere discovery that lanthanum salts remove dental plaque does not render such claims novel. However, the Opposition Division indicated in its Decision that an inventive step was regarded as being present in the claimed invention.

- IV. A notice of appeal and the statement of grounds of appeal were filed by duly confirmed telexes on 26 August 1986 and 28 October 1986 respectively. The prescribed fee was paid on 26 August 1986.

In his statement of grounds the Appellant contended that the claimed method has a clear cosmetic effect in that it cleans the teeth and thereby improves the appearance of the subject. Therefore, in view of Decision T 144/83, the Appellant considered that method claims directed to a cosmetic type of use should be allowable. Moreover, since document (1) does not disclose the use of lanthanum salts for the removal of plaque or stains, the subject-matter of claims (filed in the appeal proceedings) directed to the use of lanthanum salts for this purpose is novel, following Decision G 5/83 (OJ EPO 1985, 64).

With respect to the question of novelty of the composition claims, the Appellant contended that it was necessary to consider what had been "effectively shown" (Decision T 161/82, OJ EPO 1984, 551) by the prior document (1). There was no evidence in (1) that any dental preparation containing lanthanum had ever been brought into existence. Furthermore, a skilled reader of (1) would be faced with a choice, namely whether to choose an element such as lanthanum as an alternative to the elements disclosed in the specifically described examples, and if so, which alternative element. There was thus no effective disclosure of a dental composition containing a lanthanum salt.

- V. The Respondent maintained that the removal of plaque is not a cosmetic method since the plaque formed in the interval between normal cleaning of the teeth cannot be seen by the subject. Moreover, it is undisputed in the dental profession that plaque causes gum disorders and the formation of caries. Therefore, its prevention or removal clearly relates to a process for the therapeutic treatment of the human body.

The Respondent also argued that the use of dental care products containing lanthanum salts for the removal of plaque lacks novelty in the light of the disclosure of document (1), since the dental care products of this document inherently achieve the same purpose. Furthermore the introduction of disclaimers with respect to the Examples of document (1) in the composition claims defining toothpastes and mouthwashes does not render the subject-matter of such claims novel.

VI. In the course of the appeal proceedings the Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of any of the sets of claims in Appendices 1 to 4 filed on 2 April 1988. The claims in accordance with Appendix 1 read as follows:

"1. The use of, as the sole oral hygiene agent, a non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water-soluble salt, said composition being free of any ingredients which precipitate the cation as a water-insoluble salt for cleaning plaque and/or stains from human teeth.

2. The use as claimed in claim 1 in which the composition is in the form of a mouthwash, oral spray, toothpaste or dental gel.

3. The use as claimed in either claim 1 or claim 2 in which the lanthanum cation is present in the form of the chloride salt.

4. A non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water soluble salt, said composition being free from any ingredients which precipitate

the cation as a water-soluble salt, and being an oral spray or a dental gel.

5. A composition as claimed in claim 4 wherein the lanthanum cation is present in the form of the chloride salt.

6. A non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water soluble salt, said composition being free from any ingredients which precipitate the cation as a water-insoluble salt, and being a toothpaste but not including a toothpaste having substantially the following composition:

	Grams
Terra alba (CaSo4)	40 to 50
Gum tragacanth gel (3%)	20 to 30
Sodium salt of the sulphonic acid of the condensation product of benzene and a chlorinated kerosene fraction containing predominantly 12 carbon atoms in the chain	0.5 to 5
Glycerine	9
Saccharine	0.3
Peppermint oil	1.5
Lanthanum chloride	0.5 to 2

Water, sufficient to make up to 100 grams.

7. A non-oxidising aqueous composition which consists essentially of the unbound cation of the element lanthanum in the form of a water soluble salt, said composition being free from any ingredients which precipitate the cation as a water-insoluble salt, and being a mouthwash but not including mouthwash having substantially the following composition:

	Grams
Ethyl alcohol	20
Sodium lauryl sulphoacetate	0.5 to 5
Saccharin	0.3
Clove oil	1.0
Lanthanum chloride	0.5 to 1.0
Water, sufficient to make up to 100 grams."	

The claims in accordance with Appendices 2 and 4 are identical to Claims 1 to 3 and 1 to 5 respectively of Appendix 1.

The claims of Appendix 3 read as follows:

"1. The use of a salt of lanthanum for the manufacture of a non-oxidising aqueous mouthwash, oral spray, toothpaste or dental gel for cleaning plaque and/or stains from human teeth which consists essentially of the unbound cation of the element lanthanum in the form of a water-soluble salt and is free of any ingredient which precipitates the cation as a water-insoluble salt.

2. The use of lanthanum chloride for the use claimed in claim 1."

In his letter filed on 9 October 1990, the Respondent indicated that, although he would not be represented at the oral proceedings, he still maintained his request that the appeal be dismissed.

VII. During oral proceedings held on 13 November 1990, the Appellant contended in particular that the use claims in Appendix 1 were allowable because the claimed treatment was cosmetic not medical. Alternatively if the treatment was held to be medical, the use claims in Appendix 3 were allowable following Decision G 5/83. Composition Claims 4 and 5 in Appendix 1 were both novel and inventive over document (1), as were Claims 6 and 7 in view of the disclaimers of the specific compositions including lanthanum chloride there set out.

At the conclusion of the oral proceedings, the Board's decision to maintain the patent with an amended text as filed at the oral hearing, including claims substantially in accordance with Appendix 3, was announced. Claim 1 of the amended text corresponds essentially to Claim 1 of Appendix 3 except for the replacement of the expression "mouthwash, oral spray, toothpaste or dental gel" by the term "composition".

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. Subject to the amendments referred to in paragraph VII above, there are no formal objections under Article 123

EPC to any of the claims in accordance with the Appendices 1 to 4 since they all find a basis in granted Claims 1 to 4 (cf. also original Claims 1 to 5). As to the amendments to the claims in accordance with Appendix 3, these simply ensure that the claims in Appendix 3 correspond to Claim 1 as granted - no further amendment being necessary for the purpose of meeting the opposition (Rule 58(2) EPC).

3. Patentability - use claims

Initially it must be decided whether the claimed invention is a therapeutic or a cosmetic method of treatment. If it is cosmetic rather than therapeutic, Claims 1 to 3 of Appendices 1, 2 and 4 would not be excluded under Article 52(4) EPC. If it is a therapeutic method, such claims would be excluded from patentability, but a claim in the form of Claim 1 of Appendix 3 may be allowable following Decision G 5/83 (OJ EPO 1985, 64) as a "second medical indication", subject to questions of novelty and inventive step. Thus, a first question is whether Claims 1 to 3 of Appendices 1, 2 and 4 claim methods for treatment of the human body by therapy and are therefore excluded from patentability under Article 52(4) EPC as relating to an invention which is not susceptible of industrial application within the meaning of Article 52(1) EPC.

3.1 The Appellant submitted that the question should be decided in the negative since the removal of plaque from a person's teeth has a clear cosmetic aspect insofar as the resulting cleaner teeth improves the appearance of that person. Nevertheless, the patent in suit states at page 2, lines 35 to 37 that "plaque is generally regarded as a dominant etiological factor in caries and periodontal disease and removal of plaque from teeth or prevention of its accumulation is known to have a beneficial effect in those conditions".

In Decision T 19/86 (Pigs II/Duphar, OJ EPO 1989, 24) it was held that both prophylactic and curative treatments of diseases are within the meaning of the word "therapy" as used in Article 52(4) EPC (cf. point 7 of the Reasons). The above-quoted passage in the patent in suit implicitly acknowledges that the removal of plaque from human teeth may also be considered to be a method excluded from patentability by the terms of Article 52(4) EPC.

3.2 To support his view that Claims 1 to 3 of Appendices 1, 2 and 4 were formally allowable having regard to Article 52(4) EPC, the Appellant relied on Decision T 144/83 (OJ EPO, 1986, 301). In this case, the Board drew attention to the fact that, according to the language of the claims in question, "it clearly covers a method of cosmetic use and is unrelated to the therapy of a human or animal body in the ordinary sense. This is because loss of weight, like gain of weight is normally not dictated as a desirable effect by medical considerations at all". On the facts of the case, the Board considered that it may be difficult to distinguish between loss of weight to improve bodily appearance (cosmetic treatment) and loss of weight to treat obesity (therapeutic treatment), but that this should not be allowed to work to the disadvantage of an applicant who, according to the wording of his claim, seeks patent protection for cosmetic treatment but not for the therapeutic treatment as such. Therefore, the Board held that the fact that a chemical product has both a cosmetic and a therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable (cf. point 4 of the Reasons).

In the Board's judgment the present case should be distinguished from Decision T 144/83. Whether or not a claimed invention is excluded from patentability under

Article 52(4) EPC depends, in particular, upon the wording of the claim in question. In that case the invention as claimed was clearly directed solely to a method of treatment of the human body for cosmetic purposes; use of the claimed appetite suppressing compound in order to lose weight for medical purposes was considered as not within the scope of the claims on their proper construction. In the present case, the claimed use of a lanthanum-containing composition for cleaning plaque and/or stains from human teeth (Claims 1 to 3 of Appendices 1, 2 and 4) will always inevitably have a therapeutic effect (at least in the prophylactic sense) as well as a cosmetic effect. Thus the invention as here claimed is not directed solely to a cosmetic effect, but is also necessarily defining "a treatment of the human body by therapy" as well.

In contrast, in Decision T 144/83 a cosmetically beneficial loss of weight caused by treatment in accordance with the claimed invention of a person who is not suffering from obesity in the medical sense would not necessarily be beneficial to the health of that person, and therefore would not be a therapeutic treatment of that person.

3.3 The fact that tooth decay and periodontal diseases do not arise in the usual interval between cleaning the teeth but only become apparent over a longer time span does not render the removal of plaque a purely cosmetic treatment, since the presence of plaque on the teeth for any length of time is a detrimental factor in relation to tooth decay and periodontal diseases.

3.4 Therefore, in the Board's judgment, the invention as claimed in Claims 1 to 3 in accordance with Appendices 1, 2 and 4 is excluded from patentability under Article 52(4) EPC as not being susceptible of industrial application within the meaning of Article 52(1) EPC.

3.5 The above finding is consistent with a judgment in the United Kingdom of the Patents Appeal Tribunal in Oral Health Products Inc. (Halstead's) Applications, 1977 RPC 612, in which it was held that claims to certain methods of removing dental plaque and caries from teeth and to certain methods of preventing the formation of calculus clearly included processes for medical treatment of human beings to prevent diseases. This case was decided under the Patents Act 1949, i.e. before the EPC came into force, but the applicable law was essentially the same as that set out in Article 52(4) EPC.

4. Novelty - composition claims

The composition claims of Appendices 1 and 4 will now be considered. Claims 4 and 5 of these Appendices relate to oral sprays or dental gels comprising unbound cations of lanthanum in the form of water-soluble salts. The question to be considered under Article 54(2) EPC is whether such compositions were made available to the public by the publication of document (1), at its date of publication.

4.1 In relation to the issue of novelty, the Appellant submitted that according to document (1), the only compositions which are disclosed as having been made or brought into existence are compositions which do not include lanthanum. For this reason, he contended that document (1) does not disclose to the public any compositions which include lanthanum. He also indicated, as support for this proposition, that composition claims corresponding to those under consideration in these proceedings had been allowed following examination of a corresponding United Kingdom patent application.

In the Board's view, the question to be considered under Article 54(2) EPC when determining what is within the state of the art for the purpose of determining novelty under Article 54(1) EPC (as well as for the purpose of determining inventive step under Article 56 EPC) is not what has been "made" according to a prior document, but what has been "made available to the public" according to a prior document.

4.2 Document (1) discloses preparations for use in contact with the teeth comprising salts containing elements which are classified in Group III of the Periodic Table and which have atomic numbers from 21 to 71 inclusive, such as, for example, lanthanum (cf. Claims 1 and 9). According to this document suitable preparations are toothpastes, tooth powders, liquid dentrifices, mouthwashes and chewing gums (cf. the paragraph bridging pages 2 and 3). There is no specific mention in this document of dental gels and oral sprays, and there is no evidence before the Board that these were known at the date of document (1). In the Board's judgment it follows that dental gels and oral sprays containing water-soluble salts of lanthanum were not "made available to the public" by the publication of document (1). Therefore, the subject-matter of Claims 4 and 5 in accordance with Appendices 1 and 4 is regarded as being novel.

4.3 However, in the Board's judgment the subject-matter of these claims does not involve an inventive step in the light of the teaching of document (1). The relevant consideration in this context is the obviousness of the claimed invention at the priority date of the European patent, at which date both oral sprays and dental gels were well known. Thus, the skilled person faced with the technical problem at the priority date of the disputed

patent of providing merely differently presented compositions containing water-soluble lanthanum salts to those specifically disclosed in document (1) would obviously be able to prepare such dental care compositions which have been developed since the publication of document (1), viz oral sprays and gels, without any inventive step being required.

- 4.4 With respect to Claims 6 and 7 of Appendix 1, the Board finds that the disclaimers to the toothpaste and mouthwash exactly as described in Examples 1 and 3 respectively of document (1) do not serve to render such claims novel.

In this connection the question to be considered is again what was made available to the public, as a technical teaching, by what is disclosed in document (1).

In the Board's judgment, document (1) makes available to the skilled person by means of a technical teaching not only the specifically disclosed examples of toothpaste and mouthwash (which are "typical" examples, see page 4, line 60 and page 5, line 3) in which cerium nitrate and yttrium nitrate are replaced by lanthanum chloride, but also other typical toothpastes and mouthwashes containing water-soluble lanthanum salts. Thus, the disclaimers are not effective to avoid loss of novelty (see also Decision T 188/83 OJ EPO 1984, 555, in particular, points 4 and 5).

In relation to novelty within the meaning of Article 54(2) EPC, in the Board's view what is "made available to the public" by specific detailed examples included in a document is not necessarily limited to the exact details of such specific examples, but depends in each case upon the technical teaching which is "made available" to a skilled reader.

5. In the light of the above, none of the claims in accordance with Appendices 1, 2 and 4 are allowable.

6. Patentability of the claims in Appendix 3

The claims in accordance with Appendix 3 are in line with the formulation adopted by the Enlarged Board of Appeal in its decision G 05/83 and the six related decisions. Therefore, it must be decided whether the use of lanthanum salts for the manufacture of compositions for cleaning plaque and/or stains from human teeth is novel and inventive.

6:1 From the disclosures of both document (1) and document (3), the skilled person would be unaware of the ability of lanthanum salts to remove plaque from the surface of teeth or prevent it from adhering thereto. Thus, the acid solubility test described in these prior art documents involves the use of pure enamel which has been scraped free of deposits, and would only reveal the ability of lanthanum salts to depress the solubility of tooth enamel in organic acids (cf. (1), page 1, line 93 to page 2, line 60; (3) pages 161 and 162).

Although the skilled person would know that the use of a toothpaste in accordance with document (1) would, at least to some extent, remove plaque, he would not realise that the ability of the toothpaste to remove plaque is improved by the presence of lanthanum salts.

In the Board's view, even though both document (1) and the claimed invention are concerned with compositions for treating human teeth so as to inhibit tooth decay, the claimed invention represents a further and different therapeutic use from that disclosed in document (1),

within the meaning of Decision G 5/83 (in particular paragraph 21 thereof), because the claimed invention is based upon a different technical effect from that which is disclosed in document (1). Document (1) discloses the use of lanthanum salts in dental compositions for the purpose of depressing the solubility of tooth enamel in organic acids such as develop in saliva, thus strengthening the enamel so as to inhibit tooth decay. This is in clear contrast to the technical effect of the claimed invention, namely the improved removal of plaque from teeth by use of compositions including lanthanum salts, so as to inhibit tooth decay which would otherwise result from the presence of the plaque.

In this connection the board follows the approach set out in paragraph 10 of Decision T 19/86 (OJ EPO 1989, 24).

Thus, when a prior document and a claimed invention are both concerned with a similar treatment of the human body for the same therapeutic purpose, the claimed invention represents a further medical indication as compared to the prior document within the meaning of Decision G 5/83 if it is based upon a different technical effect which is both new and inventive over the disclosure of the prior document.

Therefore, in the Board's judgment the use of lanthanum salts to remove plaque and/or stains from teeth represents a further novel therapeutic application in accordance with Decision G 5/83, as compared to the previous disclosure of the use of such salts to depress the solubility of tooth enamel in organic acids.

6.2 With respect to inventive step, document (1) is considered to represent the closest prior art. In the light of this prior art, the technical problem may be seen in providing

a further therapeutic application for water-soluble lanthanum salts.

- 6.3 In view of the Examples in the disputed patent, it is plausible that water-soluble salts remove plaque from the surface of teeth or prevent it from adhering thereto and that the technical problem underlying the disputed patent is solved.
- 6.4 The Respondent tried to cast doubt on this by referring to a paper co-authored by Professor G. Röllä, who is one of the inventors named in the disputed patent. In this paper, which was published in the Scandinavian Journal of Dental Research, Volume 88, pages 193 to 200, 1980, it is concluded that, as a result of an investigation in which five dental students rinsed their mouths with various test solutions and then with a sucrose solution, lanthanum chloride did not significantly effect the total amount of sucrose plaque formed (cf. Abstract on page 193).

In view of the differences in protocol between the test reported in this document and, for example, Example 2 of the disputed patent and the fact that the experiments were carried out by different investigators, the Board accepts Professor Röllä's statement that the plaque index results in the paper do not negate or contradict the results in the disputed patent (cf. notes on a telephone conversation with G. Röllä filed on 10 June 1987).

- 6.5 In the Board's view, as previously stated in 6.1 above, the knowledge that water-soluble salts of lanthanum depress the solubility of tooth enamel in organic acids would not suggest to the skilled person that these salts also possess the ability to clean plaque from the surface of teeth or to prevent it from adhering thereto.


6.6 Therefore the subject-matter of Claim 1 in accordance with Appendix 3 involves an inventive step. Claim 2, which relates to a preferred embodiment of Claim 1, is also allowable.

Order

For these reasons, it is decided that:

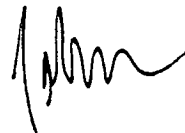
1. The decision of the Opposition Division is set aside.
2. Maintenance of the patent with claims in accordance with Appendices 1, 2 and 4 is refused.
3. The case is remitted to the first instance with an order to maintain the patent with amended text as filed at the oral hearing.

The Registrar:



M. Beer

The Chairman:



K.J.A. Jahn