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# D E C I S I O N
# of 1 February 2001

**Case Number:** T 0647/97 - 3.3.2

**Application Number:** 90312249.7

**Publication Number:** 0430474

**IPC:** A61K 9/70

**Language of the proceedings:** EN

**Title of invention:**
Sustained release compositions for treating periodontal disease

**Patentee:**
THE PROCTER & GAMBLE COMPANY

**Opponent:**
Atrix Laboratories Inc.

**Headword:**
Sustained release compositions/PROCTER & GAMBLE

**Relevant legal provisions:**
EPC Art. 56, 87

**Keyword:**
"Priority - not valid: different invention"
"Main, second, third auxiliary requests - inventive step: no - obvious to try"
"First auxiliary request - adjournment of oral proceedings until after the publication of G 2/98 - no - clear case"

**Decisions cited:**
-

**Catchword:**

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**Case Number:** T 0647/97 - 3.2.2

**D E C I S I O N**
**of the Technical Board of Appeal 3.3.2**
**of 1 February 2001**

**Appellant:** (Opponent)
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted 15 April 1997 rejecting the opposition filed against European patent No. 0 430 474 pursuant to Article 102(2) EPC.**

**Composition of the Board:**

**Chairman:** P. A. M. Lançon
**Members:** J. Riolo
S. U. Hoffmann

## Summary of Facts and Submissions

I. European patent No. 0 430 474 based on application No. 90 312 249.7, claiming priorities from two applications for US national patents, filed on 17 November 1989 (US 439066, later (Da)) and 24 August 1990 (US 573604, later (Db)) respectively, was granted on the basis of four claims.

Independent claim 1 as granted read as follows:

"1. A liquid, semi-solid or solid composition suitable for insertion into or around the periodontal pocket of a person or lower animal suffering from diseases of the oral cavity comprising a copolymer of lactide and glycolide in a concentration from about 10% to about 90% wherein the molar percentage of lactide units is from about 15% to about 85%, a drug active selected from the group consisting of antiinflammatory agents, antimicrobials, antibiotics, peroxides, anesthetic agents and vitamins in a concentration from about 1% to about 90% and propylene carbonate in a concentration from about .1% to about 90%, the ratio of the components being such that the drug active is released at a rate to provide steady state number average concentrations of from about 10 micrograms to about 2000 micrograms per millilitre of the gingival crevicular fluid of a treated periodontal pocket."

II. Notice of opposition was filed against the granted patent by the appellant (opponent).

The patent was opposed under Article 100(a) EPC for lack of inventive step.

The following documents were *inter alia* cited during the proceedings:

(1) WO-A-90/03768

(6) US-A-4 631 188.

III. The decision of the Opposition Division of 26 March 1997 posted on 15 April 1997 rejected the opposition under Article 102(2) EPC.

The Opposition Division held that the patent as granted was not entitled to the filing date of the earliest priority document (Da) in so far as it related to liquid or semi-liquid compositions. It was indeed of the opinion that this priority document envisaged only solid compositions.

Accordingly, it found that document (1), published after the filing date of (Da), represented the closest state of the art as it concerned similar compositions except for the propylene carbonate solvent.

As the available prior art documents disclosing the use of propylene carbonate as a solvent concerned neither polymers similar to the ones of the contested patent nor the same technical problems, the Opposition Division concluded that it would not have been obvious to the skilled person to combine the teachings of these documents with document (1) in order to end up with the subject-matter of the patent in suit.

IV. The appellant lodged an appeal against the said decision.

V. The respondent (patentee) submitted three sets of claims as main, second and third auxiliary request. These sets were those already filed on 27 February 1997 during the opposition proceedings.

The set of claims of the main request is identical to the set of claims as filed and as granted.

In the second auxiliary request, the words "liquid, semi-solid or solid" defining the physical states of the claimed composition have been deleted in claim 1, the other claims being identical to claims 2 to 4 as granted.

In the third auxiliary request, these words have been replaced by "solid or gel".

VI. With a fax dated 26 January 2001, the Board drew the attention of the parties to the pending question relating to the priority right (case G 2/98).

VII. Oral proceedings were held before the Board on 1 February 2001.

VIII. The submissions of the appellant both in the written procedure and at the oral proceedings, can be summarised as follows:

It first stressed that the first priority document (Da) did not concern liquid and semi-liquid compositions, and further emphasised that the problem solved by liquid and semi-liquid compositions addressed a different invention which was not the subject-matter of this priority.

It submitted that the patent in suit was concerned with two different inventions solving two different problems, ie the problem of increasing the pliability of lactide and glycolide copolymers and the problem of treating difficult-to-reach irregular areas. It argued that only the first invention, which was solved by non-fluid compositions, was entitled to the first priority.

Accordingly, it regarded document (1), which solved the problem of reaching hard-to-reach areas and of filling voids and cavities when treating periodontal pockets by using liquid compositions, as the closest state of the art with respect to the second invention of the contested patent.

It argued that the skilled person would have replaced the solvents used in the liquid copolymer compositions described in document (1) by propylene carbonate as disclosed in document (6) without inventive activity. It indeed submitted that, since this latter document concerned polymers which, although structurally different, also transformed from liquid to solid by contact with an aqueous medium and since the solvents mentioned in document (6) were largely the same as the ones recited in document (1), the skilled person would conclude that propylene carbonate would be a useful, acceptable solvent for the subject-matter described in document (1).

It also contested the validity of the experiments filed by the respondent with its letter dated 22 December 2000 as the tests did not mention whether the compared compositions contained the same copolymers.

IX. The respondent's arguments submitted both in the

written procedure and at the oral proceedings can be summarised as follows:

It submitted that, although the composition was not explicitly described as "liquid, semi-solid or solid" in the first priority application, the subject-matter of the patent in suit was nevertheless entitled to its priority date. It indeed argued that these features, relating to the physical forms of the compositions, were in fact a mere clarification that explicitly set out all the possible forms of compositions having the components recited in claim 1. As the same components in the same amounts were disclosed in the first priority application (Da), it concluded that this priority was valid.

It also maintained that the contested patent and the first priority document (Da) were concerned with the same single, broad problem, ie the formulation of compositions which could be processed effectively so that they could be placed in or around the periodontal pocket and act effectively.

It was moreover of the opinion that the claimed subject-matter was in any case inventive, even if the priority were not to be regarded as valid since the skilled person would not combine the teaching of document (1) with document (6), since this latter document related to remote polymer compositions.

It also filed a comparative experiment to show that the use of propylene carbonate as solvent led to advantageous properties in comparison with the preferred solvent disclosed in document (1).

It finally raised doubts whether the appellant was still entitled to request the revocation of the contested patent with respect to the third auxiliary request, as the appellant specifically submitted in its letter dated 17 November 2000 that the patent should be limited to this request.

X. The appellant requested that the decision under appeal be set aside and that European patent No. 430 474 be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained on the basis of the patent as granted (main request) or, if the Board did not feel able to dismiss the appeal and maintain the patent as granted and the issue of priority entitlement was relevant to that opinion, that the proceedings be adjourned until after decision G 2/98 was published (first auxiliary request), or that the patent be maintained on the basis of the first or second set of claims both submitted on 27 February 1997 (second and third auxiliary request respectively).

## Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of the appellant's request for revocation *in toto* of the patent in suit.

The Board agrees with the respondent that the appellant submitted in its letter of 17 November 1997 "that the claims of the patent-in-suit should be limited to the

second auxiliary request [ie the set of claims corresponding to the third auxiliary request of the present decision].".

This submission however does not unambiguously imply that the appellant has abandoned its request for revocation of the patent filed on 10 June 1997. There is in fact nothing else in the whole file pointing to this interpretation.

Moreover, the sentence quoted above is followed by a further requirement as to this auxiliary request, ie that the claimed compositions do not include fluid compositions. This condition is repeated *expressis verbis* on page 2, fourth paragraph, of said letter and on page 1, item 3, and page 11, item 5, of the appellant's letter dated 21 August 1997.

Since the respondent has made no request corresponding to that subject-matter, the Board is satisfied that the appellant's request for revocation of the contested patent is still valid with respect to all sets of claims provided by the respondent.

3. *Priority*

3.1 The right to priority is governed by Article 87 EPC which requires that the first application for the "**same invention**" be filed in a State party to the Paris Convention during a period of 12 months immediately preceding the filing of a European patent application.

Two applications relate to **"the same invention"** within the meaning of Article 87 EPC when they both contain **"the same subject-matter"**. This follows from

Article 87(4) EPC which uses the latter expression. The invention or subject-matter of a previous application is to be considered the same that the one of a subsequent application if the disclosure of both applications is the same.

This not only requires that the solution to a given problem is the same, but also that the problem itself is the same in both applications.

Applying these criteria, the question whether the respondent was correct in claiming the priority of 17 November 1989 should be answered, ie whether the subject-matter/invention of the contested patent, whose priority is claimed, is the same that the one of the earlier US application (Da).

As far as the "solution" is concerned (ie the features of the main claim), the Board accepts the respondent's analysis showing that the previous application, as a whole, discloses the combination of each feature of the compositions according to claim 1 of the patent in suit, with the only exception of the *expressis verbis* mention of all the possible physical states of the compositions. This was, moreover, not contested by the appellant.

It therefore remains to decide whether this *a priori* identity of solution is corroborated by the fact that the problems are the same.

The proper definition of the problem to be solved in the priority document as understood by the skilled person reading the document with his common general knowledge in the art at its filing date is decisive to

that end.

Document (Da) deals with sustained release compositions for treating periodontal disease (title, page 1, lines 1 to 3, page 4, lines 28 to 34).

According to the description on page 2, lines 18 to 29, the document aims to overcome the prior-art problems linked to the use of fiber, strips or putty-like sustained release compositions made of copolymer of lactide and glycolide, namely their limited pliability and solubility in terms of processing.

Accordingly, the problem to be solved over the prior art resides in the provision of an improved sustained-release composition with respect to its malleability for treating periodontal disease.

This problem is solved by the use of propylene carbonate either as plasticiser at low concentration, that renders the copolymer malleable, or as solvent at higher concentration, that forms gels by dissolving the copolymer (page 2, lines 30 to 32, page 6, lines 9 to 11).

The Board notes that the whole document only mentions solid and gel copolymer compositions containing propylene carbonate and that it is silent about any fluid or liquid compositions.

Having regard to the problem to be solved, the Board is moreover convinced that the skilled person reading this document could not have envisaged compositions in the two latter physical states.

As a matter of fact, the skilled person would have logically assumed that, in order to treat effectively the periodontal pocket, the sustained release composition containing the therapeutical agent needs to remain in the periodontal pocket for a certain period to be effective. He would conclude that only solids and viscous gels would provide for a sufficient delivery time in the periodontal pocket since they are difficult to dislodge.

He would accordingly not consider the compositions in the form of fluid or liquid as a suitable solution to the problem, since he would believe that they would be rapidly removed from the periodontal pocket by the crevicular fluid that flows out of the pocket.

The Board therefore concludes that the priority document is not valid for the subject-matter of the patent in suit in so far as compositions in a fluid or liquid form are concerned.

This priority is, of course, valid for the subject-matter of the contested patent dealing with non-fluid and solid compositions and solving the same problem as defined in the priority document (first invention).

As is apparent from the description of the contested patent, it is only the recognition that the fluid and liquid compositions surprisingly transform into a near solid phase in the presence of aqueous fluid such as crevicular fluid, which enables their application as sustained release compositions for treating the periodontal pocket (page 5, lines 48 to 54).

However, these compositions solve a different specific

problem, namely the problem of treating difficult to reach areas where the periodontal cavities are irregular, narrow and deep (page 5, lines 1 to 4).

This subject-matter therefore constitutes a second invention involving a different problem and a different solution.

As the priority document (Da) is completely silent about this surprising property and about the problem solved by the fluid and liquid compositions, the Board is satisfied that the patent in suit, which concerns two different inventions as shown above, is only entitled to a partial priority, ie for the first invention.

3.2 The respondent mainly submitted that, although in the first priority application the composition was not explicitly described as "liquid, semi-solid or solid", these features relating to the physical forms of the compositions, were in fact a mere clarification which explicitly set out all the possible forms of composition having the components recited in claim 1.

It also maintained that the contested patent and the first priority document (Da) were concerned with the same single broad problem, ie the formulation of compositions which could be processed effectively so that they could be placed in or around the periodontal pocket and act effectively.

3.3 It is true that the physical state of a composition primarily depends on the nature of the components present in the composition and on their respective amounts, independently of the adjective used to qualify

its physical state. The question to be answered in order to decide whether the priority is validly claimed or not is however not only to know whether a given composition can exist in a particular physical form having regard to its ingredients but rather whether the skilled person would have considered that particular state in the light of the problem to be solved. In the present case, as discussed under 3.2, the Board is convinced that the skilled person reading the priority document, without the knowledge of the disclosure of the contested patent, would have avoided fluid and liquid compositions by adding viscosity-controlling agents as advocated on page 5, line 2, of this document, as it would not regard such compositions as suitable for solving its problem.

As for the second point raised by the respondent, the Board does not deny that both fluid and non-fluid compositions according to the patent in suit solve the broad problem of providing a composition which could be processed effectively. This does not contradict the fact that each composition solves a different specific problem as shown under 3.1. In that respect, the Board points out that it is always possible to determine a common problem to be solved by different inventions provided its definition is broad enough. This approach could however only accepted in the case the broad problem was never solved in the prior art.

The Board also notes that, as it clearly appears from the description of the patent in suit, it is the recognition of the fact that the fluid compositions transform into near solid in the presence of aqueous fluid that made it possible for the skilled person to envisage fluid compositions as a new solution of the

broad problem defined above. This observation was however made at a later stage as is apparent from the fact that the derived specific technical problem as well as its related "fluid" solutions were made the subject-matter of the second priority document (Db).

Accordingly, this latter argument cannot be taken into account either for the assessment of the priority right.

4. *Main request*

4.1 Article 123(2) and (3) EPC

No objection under Article 123(2) and (3) EPC was raised by the appellant against the set of claims of the main request, which correspond to the set of claims as filed and as granted. The Board sees no reason to object.

4.2 Novelty

No objection under Article 54 was raised against this set of claims during oral proceedings and the Board sees no reason to differ.

4.3 Inventive step

4.3.1 The patent provides for sustained-release compositions for treating periodontal disease. Claim 1 of the contested patent claims copolymer compositions which are either non-fluid (solid and non-fluid gel) or fluid (liquid and fluid gel). As shown under point 3, only the first subject-matter relating to non-fluid compositions is entitled to the priority right of

document (Da).

Document (1) relates also to liquid compositions for treating periodontal disease (page 2, lines 20 to 25, page 2, line 33, to page 5, line 4).

Although it was published after the filing date of the priority document (Da), this document belongs however to the state of the art with respect to the second subject-matter of the contested patent as this subject-matter is not entitled to the priority right of (Da) (see point 3).

The Board considers therefore that document (1) represents the closest prior art with respect to the second subject-matter of the patent in suit, ie with respect to the fluid and liquid compositions.

4.3.2 Example 6 of this document, for instance, describes a liquid composition comprising a copolymer of lactide and glycolide in a concentration from about 10% to about 90% wherein the molar percentage of lactide units is from about 15% to about 85% (ie 50:50 ratio of the two monomers), a drug active antimicrobial agent in a concentration from about 1% to about 90% (ie 2% sanguinarine chloride, benzophenanthridine alkaloid with antimicrobial activity towards periodontal pathogens) and N-methyl-2-pyrrolidone (NMP)in a concentration from 0.1% to about 90% (ie 70% by weight polymer solution).

According to the description, the compositions of document (1) can be placed in the periodontal cavity where they solidify into a solid structure in the presence of water. The document discloses moreover that

the release of the drug follows the general rules for diffusion or dissolution of a drug from within a polymeric matrix (page 2, lines 20 to 25, page 2, line 33, to page 5, line 4, page 5, lines 14 to 16).

Having regard to the patent in suit, the drug active is released at a rate to provide steady-state number average concentrations of from about 10 micrograms to about 2000 micrograms per millilitre of the gingival crevicular fluid of a treated periodontal pocket. The respondent did not contest that these steady rates were also achieved by the compositions of document (1).

Accordingly, the only difference in the claimed compositions of the patent in suit and the compositions of the prior art document (1) lies in the presence of propylene carbonate as a solvent instead of NMP.

As to the experiments filed by the respondent with its letter dated 22 December 2000, the Board notes that the tests do not mention whether the compared compositions contain the same copolymers. In that respect, the respondent stated in the letter accompanying the comparative example that "the comparison between the two products is not an exact comparison, since the amounts of solvent are not the same and I believe the polymers are not the same". Since it is well-known that the polymer composition directly influences the properties of the compositions, as confirmed for instance by document (1), the comparative experiments cannot be taken into account for the assessment of inventive step and in particular for the definition of the problem to be solved (page 9, line 32, to page 10, line 2).

It follows that the problem to be solved as against document (1) can only be seen as the provision of an alternative liquid sustained-release composition for treating periodontal disease.

4.3.3 This problem is solved by the subject-matter of claim 1, when relating to liquid and fluid compositions and, in the light of working examples 3 to 5 of the patent in suit, the Board is satisfied that the problem has been solved.

4.3.4 Thus, the question to be answered is whether the proposed solution, ie the replacement of the solvent NMP by propylene carbonate, was obvious to the skilled person in the light of the prior art.

Document (1) requires the solvents to be used to dissolve the biodegradable lactide-glycolide copolymer to be non-toxic and water miscible. A list of suitable solvents is given in the document (page 9, second paragraph). This document is however silent as to the use of propylene carbonate as an alternative solvent for NMP.

Document (6) deals with liquid compositions of non-biodegradable polymers in a solvent, which also transform from the liquid to near the solid state *in situ* in the presence of water and which may also contain biologically active substances (column 2, lines 25 to 35, column 4, lines 16 to 24).

Like document (1), document (6) merely requires the solvents which are to be used to dissolve the non-biodegradable polymer to be non-toxic and water miscible. A list of suitable solvents is given in the

document (column 3, lines 38 to 55). There is moreover a clear overlap between the suitable solvents cited in document (6) and those of document (1), and propylene carbonate is mentioned *expressis verbis* as a suitable one.

Accordingly, as in the case of an alternative solution the skilled person remains free to choose any suitable solvent *a priori*, the Board is satisfied that the skilled person would replace the solvent NMP disclosed in document (1) by propylene carbonate without an inventive activity being involved since most of the solvents disclosed in document (6) are equally suitable for the compositions described in document (1) and since the general requirements for the solvents are identical in both documents.

4.3.5 The main arguments raised by the appellant were that the skilled person would not consider ethylene carbonate as a suitable solvent for two reasons, namely because it was less water soluble that the four preferred solvents mentioned in document (1) and because document (6) related to completely different polymers, ie non-biodegradable polymers, so that the skilled person would not expect the solvent to be also suitable for biodegradable polymers.

It also maintained that propylene carbonate was in any case better than NMP as a solvent because of its ideal behaviour with respect to its rate of diffusion into the body fluids, which provided for a slow coagulation of the polymer allowing an appropriate insertion of the composition into the periodontal pocket before full hardening occurred.

4.3.6 The Board cannot share the opinion of the respondent.

The Board does not contest that certain solvents listed in document (1) might be more water-soluble than propylene carbonate. There is however not such a general teaching in document (1) which would prevent the skilled person from using a water-soluble solvent which is less soluble than NMP since the only requirement in this document is that the solvents must be water-**miscible** and since the solvents listed in document (1) obviously cover a wide range of water-solubility as shown by the water-solubility data provided by the respondent with its letter of 22 December 2000.

Nor does the Board accept the argument that the skilled person would not consider the solvents disclosed in relation with non-biodegradable polymers for dissolving biodegradable polymers. As a matter of fact, solubility and biodegradability of polymers are two different issues which are not necessarily linked. The solubility of a polymer in a given solvent follows the well-know adage in chemistry “like dissolves like”, which means that its solubility depends primarily on the polarity of its functional groups, whereas its biodegradability depends on the ability of the polymer to be cleaved by enzymes.

In the present case, the fact that there is a clear overlap between the solvents listed in document (1) and the ones listed in document (6) constitutes a clear indication that there is also an overlap with respect to the solubility of biodegradable and non-biodegradable polymers, with the result that the skilled person would also consider these latter solvents as suitable for dissolving biodegradable polymers.

As regards the last point, the Board notes that the alleged effect has not been substantiated, with the result that it cannot be taken into account for the assessment of inventive step (see point 4.3.2).

In view of the foregoing, the Board concludes that the subject-matter of claim 1 of the main request does not involve an inventive step as required by Article 56 EPC.

5. *First auxiliary request*

As discussed under point 3, the Board has no difficulty to recognize that the subject-matter of the priority document (Da) and the second subject-matter of the contested patent clearly relate to two **different** inventions.

Accordingly, there is no need to adjourn until after decision G 2/98 is published and the first auxiliary request is therefore rejected.

6. *Second and third auxiliary requests*

6.1 Article 123(2) and (3) EPC

No objection under Article 123(2) and (3) EPC was raised by the appellant against the set of claims of the second auxiliary request and the Board sees no reason to object.

In fact, the deletion of the words "liquid, semi-solid or solid" does not affect the subject-matter of claim 1 as, in the present case, all compositions having the defined components can only be either liquid, semi-solid or solid.

No objection under Article 123(2) and (3) EPC was raised by the appellant against the set of claims of the third auxiliary request either and the Board sees no reason to object.

6.2 Novelty

No objection under Article 54 was raised against these sets of claims during oral proceedings and the Board sees no reason to differ.

6.3 Inventive step

The findings under 4.3.4 also hold good for the second auxiliary request, as liquid compositions are part of its claim 1.

In respect of the third auxiliary request, the Board stresses that the term gel used in claim 1 encompasses physical states ranging from the solid state up to the

fluid state, which is very similar to the liquid state. This is moreover confirmed by the description of the contested patent (eg page 5, lines 46 to 49).

Since the fluid compositions are not entitled to the priority right of document (Da) as discussed under point 3, document (1) remains relevant as the closest state of the art as far as gel-like fluids covered by claim 1 are concerned.

Having regard to the great similarity of behaviour between the liquid compositions and the gel-like fluids, the Board concludes that the findings under 4.3.4 also hold good for the third auxiliary request.

## 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:

A. Townend P. Lançon