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**D E C I S I O N**  
**of 17 July 2002**

**Case Number:** T 0069/99 - 3.3.2

**Application Number:** 91908723.9

**Publication Number:** 0522087

**IPC:** C01B 15/00

**Language of the proceedings:** EN

**Title of invention:**  
Methods for treating teeth surfaces

**Patentee:**  
ULTRADENT PRODUCTS, INC.

**Opponents:**  
Discus Dental Inc.  
VOCO GmbH

**Headword:**  
Dental tray/ULTRADENT

**Relevant legal provisions:**  
EPC Art. 100(c), 123(2), 100(a), 56

**Keyword:**  
"Main request - first to fifth and seventh to fourteenth  
auxiliary request - unallowable amendments - opposition under  
Article 100(c) EPC not waived"  
"Sixth auxiliary request - inventive step (no) - mechanical  
and chemical aspects - obvious solution"

**Decisions cited:**  
-

**Catchword:**

-



Case Number: T 0069/99 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 17 July 2002

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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 1 December 1998  
revoking European patent No. 0 522 087 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon

**Members:** U. Oswald

C. Rennie-Smith

## Summary of Facts and Submissions

- I. European patent No. 0 522 087 based on the international application No. PCT/US91/01794 was granted on the basis of 29 claims.

Claims 1 and 16 relating to a method and an assembly read as follows:

- "1. A method of bleaching a patient's teeth as a cosmetic treatment, which comprises:

(a) providing a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, the dental bleaching composition comprising:  
a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with the dental bleaching agent; and  
a matrix material into which the dental bleaching agent is dispersed, the matrix material conferring tacky characteristics on the composition, and including carboxypolymethylene in an amount such that the matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours;

(c) positioning the dental tray over the patient's teeth surfaces so that the dental bleaching

composition is in contact with the patient's teeth surfaces to be bleached;

(d) retaining the dental tray in position over the patient's teeth surfaces by virtue of the tacky characteristics of the bleaching composition; and

(e) removing the dental tray from the patient's teeth.

16. An assembly for providing dental bleaching of a patient's teeth, which comprises:

(a) a dental bleaching composition comprising:  
a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with the dental bleaching agent; and  
a matrix material into which the dental bleaching agent is dispersed, the matrix material conferring tacky characteristics on the composition, and including carboxypolymethylene in an amount such that the matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours; and

(b) a dental tray to be fitted over the patient's teeth so as to cover them, and configured to hold a quantity of the dental bleaching composition."

II. Opposition was filed against the granted patent by both Respondent 01 and Respondent 02 on the grounds of inventive step under Article 100(a) EPC, and additionally opposed by Respondent 02 under Article 100

(c) EPC on the grounds that the feature  
"*...carboxypolymethylene in an amount such that the matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours;...*"

extends beyond the content of the application as filed. It was particularly pointed out that the application as originally filed exclusively related to a bleaching composition including carboxypolymethylene in an amount of about 3.5% to about 12% by weight of the bleaching composition

III. By a decision announced on 12 November 1998, and posted with written reasons on 1 December 1998, the Opposition Division revoked the patent under Article 102(1) EPC.

The Opposition Division did not uphold the opposition under Article 100(c) EPC since in particular the passage at page 13, lines 7 to 14 of the application as filed disclosed a basis for replacing an amount of carboxypolymethylene ascertained by weight (about 3.5% to about 12% by weight of the bleaching composition) with an amount ascertained by the result to be achieved (see the feature cited in section II above). This passage indicated clearly that the effect that was sought by the method of treatment is achievable over a period of time greater than 3 hours.

The following documents were cited:

- (1) Haywood et al, "Nightguard Vital Bleaching"  
published in *Quintessence International*, Vol. 20,

No. 3 (March 1989) pages 173 to 175,

(2) US-A-3657413,

(7) *Clinical Research Associates Newsletter*, Vol. 13,  
Issue 12 (December 1989).

In the Opposition Division's view the subject-matter of claim 1 of the main request (corresponding to claim 1 as granted) lacked novelty over document (1) or document (7).

More particularly, it was held that the prior art would also show tacky characteristics of the matrix material which to some degree would hold the dental tray in place on patients' teeth. The feature relating to carboxypolymethylene in an amount such that the matrix material provided for bleaching agent to be in contact with the tooth surfaces for more than 3 hours did not distinguish the subject matter of the patent in suit from the relevant prior art disclosing dental trays as night guards because compositions contained in such trays could be expected to remain in contact with the teeth for over 3 hours, notwithstanding leakage.

As regards the auxiliary request (so-called subsidiary request III), the Opposition Division found that the amendments to claims 1 and 15 relating to the extrusion of the composition from a container did not fulfil the requirements of Articles 84 EPC and 123(2) EPC and considered that the subject-matter of these claims lacked novelty over the cited prior art.

Independent claims 2 and 13 of subsidiary request III relating to a method and assembly comprising, in



addition to the granted version of the claims, the feature *that the dental tray having scalloped configuration so that it can cover the patients tooth surfaces while not covering the interdental papillae*, however, were considered to be novel but not inventive. In addition to the cited documents, the Opposition Division relied on an expert's statement during the oral proceedings that dental trays with scalloped configurations were well-known in the art at the relevant date of the patent in suit.

The Opposition Division based its reasoning inter alia on the following:

- (i) that the expert's statement was not challenged by the Appellant,
- (ii) that particularly in the light of the disclosure of document (7), page 2, "Summary of Data in Chart", it was obvious to increase the viscosity of the matrix material of the bleaching composition,
- (iii) that increasing the viscosity by increasing the amount of carboxypolymethylene at the same time gave a greater tackiness to the whole bleaching composition,
- (iv) that greater tackiness of the composition kept the tray in position on the patient's teeth so that the skilled person would thereby solve the problem of longer retention of the bleaching composition in the dental tray, thus allowing for use of a lighter tray.

IV. The Appellant appealed against this decision. After the Appellant had by its letter of 29 May 2001, substantiated its allegation that infringement of the patent might be taking place, the Board accelerated the appeal proceedings. On 17 June 2002, the Appellant filed a new main request and 29 auxiliary requests, each comprising a set of 29 claims.

Oral proceedings took place on 17 July 2002. The Appellant's request to present its case partly by means of an audio-visual presentation was refused since neither the Board nor the Respondents were informed in advance of the oral proceedings that the proposed video presentation would be limited to a presentation of argument and would not include matters of evidence.

After discussing formal aspects of the newly filed requests, particularly the question whether in the circumstances of the case, claims in the two-part form of the claims appeared to be the best manner of characterizing the invention, the Appellant withdrew the main request and auxiliary requests 1 to 14 filed on 17 June 2002, the claims of which were drafted in the two part form.

The Respondents did not object to the admissibility of the remaining requests 15 to 29 in the form of a new main request and auxiliary requests 1 to 14.

Claim 16 of former auxiliary request 21, now the sixth auxiliary request, reads as follows:

"16. An assembly for providing dental bleaching of a patient's teeth, which comprises:

(a) a dental bleaching composition comprising:  
a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with the dental bleaching agent; and  
a matrix material into which the dental bleaching agent is dispersed, the matrix material conferring tacky characteristics on the composition, and including carboxypolymethylene in an amount from about 3.5% to about 12% by weight of dental bleaching composition such that the matrix material has a sufficiently high viscosity and low solubility in saliva that when the composition is placed within a dental tray that is formed from a thin, soft flexible material and that is trimmed barely shy of the patient's gingival margin and that is scalloped up and around interdental papilla so that the finished tray does not cover the papilla, the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours; and

(b) a dental tray to be fitted over the patient's teeth so as to cover them, and configured to hold a quantity of the dental bleaching composition."

V. After the parties were informed that, for the purposes of Article 54 EPC, a combination of the disclosures of different documents, even though dealing with very closely related matter, was unallowable, novelty of the claimed subject-matter of each of the requests was agreed by the Respondents.

VI. The arguments of the Appellant, both during the written procedure and at the oral proceedings, may be summarised as follows:

Taking into account the disclosure of the originally filed PCT-application as a whole, it was clear that the amount of carboxypolymethylene of 3.5% to 12% by weight of the dental bleaching composition did not represent an essential feature of the invention. A specific basis for replacing the specified amount of carboxypolymethylene by the now claimed combination of functional features could be found on page 4, lines 28 to 34; page 5, lines 1 to 3, 9 to 11 and 19 to 27; page 8, lines 24 to 27 and page 9, lines 9 to 16 and 24 to 29.

The decision of the Opposition Division was based on a wrong interpretation of the prior art disclosure. The use of scalloped trays in relation to the treatment of teeth surfaces using techniques of the type with which the patent in suit was concerned was neither disclosed by any of the prior art documents nor was it part of the common general knowledge as alleged by one expert's opinion. The Opposition Division ignored the fact that the bleaching compositions of the prior art documents would leak out of the tray unless the tray overlapped the gums. The bleaching compositions which were considered in documents (1) and (7) were runny compositions which had a low tackiness and protection from displacement was provided by use of a tray which was relatively stiff and resulted in significant discomfort for the user. Document (1) clearly described a 2 mm thick nightguard similar to an athletic mouthguard. The stiff prior art trays allowed only mechanical sealing by abutting the edge of gingival tissue and thus caused orthodontic forces on the teeth. Moreover, document (7) neither disclosed a flexible tray material nor taught to trim the tray barely shy of the patient's gingival margin.

Accordingly, in the light of the prior art disclosures and starting from document (1) as the closest prior art, the invention of the patent in suit solved a plurality of problems namely, keeping saliva from diluting the bleaching composition, avoiding the composition running out and being swallowed, positioning the tray without imposing mechanical forces on the teeth surfaces and, as an overall result, good sealing of the tray by minimizing patient discomfort.

All these inconveniences were undoubtedly avoided when using a thin soft flexible tray material which is trimmed and scalloped as defined in the claims and held in place by an adhesive composition.

The prior art did not give the slightest hint to include such a high amount of carboxypolymethylene in the bleaching composition in order to achieve the high viscosity which was necessary to solve the stated problems. Documents (1) and (7) clearly described dropwise application of Proxigel which could only imply a high fluidity of the matrix material of the composition. Moreover, point 4 of the "Summary Of Data In Chart" of document (7) disclosed only in relative terms a higher viscosity of Proxigel in comparison with nearly aqueous non-viscous materials but not a high viscosity as defined in the now claimed invention. The bleaching composition of the invention represented, in contrast to the prior art compositions, an extrudable material as a result of the use of modified Proxigel. Finally, it was pointed out that in contrast to the surprising effect of three hours of bleaching activity on the teeth surface according to the invention, the method and the use of materials disclosed in document (7) implied frequent replenishment of the bleaching

composition in the tray and merely 40 to 60 minutes of bleaching action.

Even assuming, which was strongly contested, that document (7) disclosed that a person skilled in the art could increase the viscosity, the prior art gave him no incentive to do so in order to solve the stated problems.

Document (2) published in 1972, a long time before the priority date of the patent in suit, contained a clear teaching that by increasing the viscosity deleterious effects on tissue were to be expected, in particular having regard to the fact that document (2) disclosed that carboxypolymethylene imparts greater tissue adherence characteristics on solutions. Accordingly, there was a strong prejudice against using a matrix material with the high viscosity of the invention. This was proven by several experts' opinions to the effect that the application of carboxypolymethylene to tissue should be avoided. Even assuming that an ordinary dentist would have been prompted to look at document (2), the suggestion of an increased adherence of an antiseptic composition to soft tissue would not have suggested using tackiness of a bleaching composition to make a plastic tray adhere to teeth. Moreover, for practical purposes, document (2) taught amounts as low as 0.4 to about 1.5 weight percent (based on total weight of the composition) of polymer.

VII. The Respondents' arguments may be summarised as follows:

Since only claim 31 as originally filed represented the relevant disclosure of the functional features opposed

under Article 100(c), but that claim 31 contained a specific reference back to claim 22 as originally filed relating to a matrix material necessarily including carboxypolymethylene in the range from about 3.5% to 12% by weight of the dental bleaching composition, the Appellant's reference to a general disclosure in the description as a whole was no answer to this ground of opposition.

Relative terms, such as "thin", "soft", "flexible", "barely shy", "scalloped up and around" and "concentrated", lacked clarity under Article 84 EPC, particularly when used to delimit the claimed subject-matter against the prior art.

The problem underlying the alleged invention could only be seen as the avoidance of soft tissue irritation resulting from intimate contact of dental bleaching trays and dental bleaching compositions over a prolonged period of time with soft tissue in the mouth.

This problem, however, had already been recognised in document (7) (see item F on page 1738), clearly indicating that carboxypolymethylene containing tooth bleaching products affected gingival fibroblast cultures adversely and any subsequent development of dental trays by cutting them back to avoid contact between the soft tissue and the bleaching agent inevitably led to tray configurations as now claimed.

There was no basis for the assumption that documents (1) and (7) related exclusively to rigid tray material since this prior art expressly referred to a "soft plastic nightguard".

It was obvious to a skilled person to further increase the viscosity of the bleaching composition by increasing the amount of carboxypolymethylene therein because the claimed matrix material carboxypolymethylene was a well-known thickening agent suitable for achieving a high viscosity and stickiness or tackiness of compositions. This was taught by document (2) which disclosed viscosity ranges up to 500000 centipoise of extremely stiff gels for compositions with up to 5% of this thickening agent. Further document (7) contained clear technical information that more viscous compositions prevented run off and pooling and led to less saliva dissolution and swallowing than less viscous compositions. It was also observed that the composition of document (1) was commercially available under the trade name Proxigel and that the package in which Proxigel was sold carried a clear reference to document (2).

These arguments of the Respondents applied as a whole to the subject-matter both of the claims relating to the method as well as to the claims to a dental bleaching assembly.

VIII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the new main request or alternatively one of auxiliary requests 1 to 14 filed during the oral proceedings.

The Respondents requested that the appeal be dismissed.

## **Reasons for the Decision**



1. The appeal is admissible.
2. The new main request and each of the new auxiliary requests 1 to 5 and 7 to 14 still contain the functional feature opposed under Article 100(c) EPC, namely that the bleaching composition includes *"...carboxypolymethylene in an amount such that the matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours;..."*.

Page 13, lines 8 to 15 of the application as originally filed did indeed contain a reference to *"..3 to 7 hours of normal day time activity and after 7 to 10 hours of sleep..."* but certainly did not disclose any period of time longer than about 3 hours without any other limitation of time.

The Board notes that, of the claims as originally filed only claim 31 relates to *"a method for bleaching a patient's teeth...wherein the dental tray remains positioned over a patients teeth for a period of time greater than about 3 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surface"* and thus relates to a period of time greater than about 3 hours. This claim, however, depends on claim 22 as originally filed and incorporates all the restrictions required by the independent claim.

The other passages of the application document referred to by the Appellant do not contain any reference to a

precise period of time over which the claimed functions are to be achieved.

Accordingly, the only basis for the functional features under discussion is that found in claim 31 in combination with claim 22 as originally filed, which also requires an obligatory amount of 3.5% to 12% of carboxypolymethylene in the bleaching composition. Therefore it can only be concluded that each of the sets of claims of the new main request and auxiliary requests 1 to 5 and 7 to 14 do not fulfil the requirements of Article 123(2) EPC and as a consequence each of those requests must be refused.

3. The sixth auxiliary request is the only request which does not rely on a pure functional relationship between the period of time of the contact of the bleaching agent with the tooth surfaces and the amount of carboxypolymethylene but defines a concrete range of the amount of carboxypolymethylene to be included in the matrix.

The subject matter of claim 16 of the sixth auxiliary request (see point IV above), the broadest and independent product claim, can be derived from claims 22 and 31 as originally filed in combination with page 9, lines 9 to 16; page 11, lines 27 to 30 and page 15, lines 9/10 and lines 14 to 16. The method claim 1 of the sixth auxiliary request is also based on the same disclosures.

The Board is also satisfied that each of the dependent claims 2 to 15 and 17 to 29 of the sixth auxiliary request has a basis in the application as originally filed.

Moreover, having regard to the inclusion of an obligatory amount of 3.5% to 12% of carboxypolymethylene in the bleaching composition of independent claims 1 and 16, the subject matter of the whole set of claims 1 to 29 of the sixth auxiliary request is also restricted in comparison with the set of claims 1 to 29 as granted.

Accordingly the requirements of Articles 123(2) and (3) EPC are fulfilled for the sixth auxiliary request and the grounds of opposition under Article 100(c) EPC can be considered overcome for the purposes of this request.

4. The Respondents put forward strong objections under Article 84 EPC against relative terms such as "thin", "soft", "flexible", "barely shy", "scalloped up and around" and "concentrated", when used to delimit the claimed subject-matter against the prior art.

The Board, however, sees *a priori* no reason to refuse under Article 84 the use of such relative terms when defining the subject-matter for which protection is sought. Rather it emphasises the fact that for the purpose of examination under the requirements of the EPC in the light of the prior art in the absence of more precise definition in the application as filed, relative terms should be interpreted in their broadest technically meaningful sense. Accordingly, in the absence of any specific mechanical parameter, the term "flexible" as such means any property of a material which is not absolutely rigid.

5. At the oral proceedings before the Board the Respondents agreed that none of the cited documents

taken alone disclosed the combination of features of the independent claims of the new requests and accordingly the Board sees no reason to consider further the application of Article 54 EPC to the sixth auxiliary request, particularly since none of the documents discloses a trimmed and scalloped dental tray which contains carboxypolymethylene in amounts as defined in the independent claims 1 and 16.

6. Although the Respondents presented some arguments regarding the obviousness of the subject-matter of the patent in suit by starting from document (7), during the oral proceedings the parties agreed that document (1) represents the suitable starting point for the assessment of inventive step under Article 56 EPC.

Document (1) is concerned with a method of "nightguard vital bleaching". Vital bleaching is described as a viable option in aesthetic dentistry to be considered when treating intrinsically stained or discoloured teeth whose form and integrity are deemed acceptable (page 173, left column, "Introduction"). The method requires the manufacture of an alginate impression of the arch to be treated. From the resultant hydrocol cast, a vacuum formed soft plastic night guard, approximately 2mm thick (similar to an athletic mouthguard) is fabricated. The nightguard should completely cover all the teeth in the arch, while leaving the palate and as much contiguous gingival tissue as possible uncovered. This design is recommended both for patient comfort and for minimizing potential injury to the soft tissue. Try-in of the nightguard to assess the accuracy of fit and to verify that no rough edges exist is recommended. Following

initial try-in, the nightguard is adjusted with a slow handpiece to ensure uniform distribution of occlusal contacts (see page 173, last paragraph to page 175, first paragraph).

On page 174, "Figure 3" shows a patient wearing a soft nightguard. The accompanying description reads "The soft nightguard covers each tooth entirely with only minimal soft tissue coverage".

Points 2 and 4 of the patient instructions on page 175, left column, read as follows: "Place 2 to 3 drops of carbamide peroxide (Proxigel, Red & Carnick Pharmaceuticals) into the space in the nightguard for each tooth to be lightened"; "Wear the loaded nightguard during sleep every night until treatment is complete".

Finally, under the heading "discussion" on page 175, right column, it is said that no long term detrimental effects upon the teeth or gingiva had been observed with this bleaching technique. Patients reported either no sequelae or only mild transient discomfort. No long-term deleterious effects had been observed to date (i.e. the date of the document). There had been no patient reports of significant tissue problems, odour, or bad taste associated with the procedure.

7. In defining the problem to be solved by the subject-matter of the claims of the sixth auxiliary request as against document (1), it is necessary to consider claim 16 relating to an assembly for providing dental bleaching and thus a product per se since this claim seeks a broader scope of protection than the method claim 1.

7.1 The Board notes that claim 16 does not refer back to the method of claim 1 and does not comprise the feature of claim 1 "retaining the dental tray in position over the patient's teeth surfaces by virtue of the tacky characteristics of the bleaching composition". The relevant passages of claim 16 only comprise the requirement that "the matrix material conferring tacky characteristics on the composition" and that the matrix material provides for "the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours". Neither of those features inevitably require that the bleaching composition be sufficiently tacky to retain the dental tray in position over the patient's teeth without any mechanical impact or fitting of the tray onto the teeth surfaces.

7.2 The references on page 2, lines 24 to 36 and lines 44 to 50 of the description of the patent in suit show some disadvantages of the bleaching method of document (1), disadvantages which are inevitably related to a leakage problem of the tray used in document (1). In writing and during the oral proceedings both the Appellant and the Respondents referred in various ways to the leakage problem inherent in the use of the tray shown in Figure (3) of and described in document (1).

Furthermore, as was common ground between the parties and as was indicated by patients' reports, the method and hence the tray of document (1) causes some discomfort in use. The picture in Figure (3) of document (1) undoubtedly shows some contact of the soft tissue of the gum with tray edges and indeed the description of "Figure 3" does not indicate whether the tray shown there has already been adjusted as indicated

in the corresponding passages of the text.

- 7.3 In view of the foregoing, the problem underlying the patent in suit can be seen as the provision of a dental bleaching assembly including a dental tray which is sufficiently tight-fitting so as to reduce leakage of the bleaching composition while preventing saliva dilution and minimizing patient discomfort.

This problem is solved by the amount of carboxypolymethylene and the configuration of the tray as set out in claim 16.

The Board notes that the wording of said claim 16 "*...in an amount from about 3.5% to 12% by weight...such that...*" clearly requires that each of the functional features of claim 16 are fulfilled when carboxypolymethylene is present in an amount of 3.5% to 12% by weight of the dental bleaching composition.

Having regard to example 1 of the patent in suit, which includes a reference to a dental tray such as that described in connection with Figures 1 to 4 of the patent in suit and worn by a patient for 9 hours, the Board is satisfied that the stated problem has been plausibly solved.

- 7.4 It remains therefore to consider whether the claimed solution involves an inventive step.
- 7.4.1 Any dentist would undoubtedly consider the "Clinical Research Associates" newsletters which provide the dental profession with research results, and would thus be aware of document (7), an update report which provided an overview of the performance of various

bleaching agents.

On page 1737, under the heading "SUMMARY OF DATA IN CHART", point 4, document (7) discloses a list of various bleaching agents, one of which is Proxigel. These agents are characterised as having "higher viscosity that prevented run off & pooling & minimized saliva dilution & swallowing". The same technical information can be derived from the table on top of page 1737 under column "PRODUCT NAME", point 7, Proxigel.

The Board agrees with the Appellant's submission that the reference to higher viscosity in document (7) means higher than nearly aqueous non-viscous materials and that this report discloses several disadvantages such as hourly replenishment (point F on page 1736), bleaching activity of only 40 to 60 minutes (last paragraph point C on page 1737), and tissue problems on page 1738, point F on top of page) but only when using the Proxigel product as then available on the market.

Notwithstanding the problems associated with home-use bleaching and Proxigel as sold commercially at the date of document (7), the dentist would obtain from document (7) the clear information that the viscosity of the bleaching agent plays a key role in phenomena such as run off or saliva dilution of the bleaching composition, which (phenomena) can be ascribed to the fact that the dental trays then in use suffered from leakage problems.

7.4.2 Once the dentist had recognized the relevance of the chemical, or more precisely the physico-chemical nature of the solution to this part of the problem, he would



turn with this document (7) to a chemist who is the skilled person to whom the problem must be addressed.

The chemist, as the relevant person skilled in the art, would know from several disclosures and from his common general knowledge in the field, that Proxigel not only contains the bleaching component carbamide peroxide referred to in document (1) but is also a composition of a plurality of components including carboxypolymethylene polymer as a matrix material mainly responsible for the viscosity and drug release properties of the composition.

- 7.4.3 Accordingly, the skilled person's particular attention would be drawn to document (2) since it relates to antiseptic compositions in the field of dentistry including urea peroxide (carbamide peroxide) and carboxypolymethylene (see claim 1), in other words a method of treating the mucous membranes of the oral cavity by a composition comprising essential components as proposed in document (1) for tooth bleaching.

Document (2) includes the clear teaching "that it has been found that not only do carboxypolymethylene polymers serve as effective thickening agents for solutions of urea peroxide in glycerol, but surprisingly, these polymers impart sustained nascent oxygen release effects to such solutions and, moreover impart greater tissue adherence characteristics thereto" (see column 2, lines 36 to 44). Document (2) describes the use of alkanolamine neutralized and commercially available carboxypolymethylene polymers such as Carbopol 934 and 940 (see examples 1 and 2), the same type of polymer used in the patent in suit.

According to the passage from column 3, lines 66 to column 4, line 5, the concentration of neutralized carboxypolymethylene polymer may be varied in order that the finished composition ranges in viscosity from a thickened syrup-like liquid of about 1000 centipoise at room temperature (about 24°C) to extremely stiff gels with viscosities of 500000 or more centipoise at room temperature. In general amounts of from 0.05 to about 5 weight percent (based on total weight of the composition) of polymer are employed.

Contrary to the Appellant's argument as to the preferred amount of 0.4 to about 1.5 weight percent (based on total weight of the composition) of polymer employed, the Board sees no reason to exclude the upper percentage value of 5 weight percent from the teaching of document (2), particularly since that document refers to "extremely stiff gels".

- 7.4.4 It follows that there is no reason why the skilled person faced, with the leakage problem as stated above, would not modify the composition of document (1) by adjusting the viscosity as suggested by document (7) and thereby be lead to further increase the viscosity by increasing the amount of carboxypolymethylene up to an maximum amount of 5 weight percent as described in document (2) if necessary, until the dental tray would be sealed by a stiff gel.

The reference in document (2) to tissue adherence clearly implies tacky characteristics of the composition. Low solubility in saliva was mentioned in document (7) and claim 16 requires even for an amount of carboxypolymethylene as low as 3.5% (a lower amount than the 5% found in document (2)), that the bleaching

agent be in contact with the tooth surfaces over a period of time greater than about 3 hours. Claim 16 does not refer to the quantity of bleaching agent.

In these circumstances the Board can only conclude that the skilled person prompted by the disclosures in documents (1), (2) and (7) to include in the composition of document (1) the maximum amount of carboxypolymethylene of 5 weight percent of the total composition, would inevitably achieve each of the functions of the bleaching composition of claim 16 of the sixth auxiliary request without the exercise of inventive skill. Hence, the dentist thus advised would obviously solve the essential aspect of the problem defined above (see point 7.3).

- 7.4.5 The remaining part of the problem mentioned under 7.3 above is in the view of the Board a mere matter of optimisation of the teaching of document (1). The Board agrees with the Appellant's submission that Figure 3 of document (1) shows a tray which abuts the edge of gingival tissue. It appears furthermore plausible that such a tray configuration may cause discomfort. However, the colour photographs of document (1) cannot be taken as the exhaustive implementation of the teaching of this document. They are merely selected examples of the teaching of document (1) as implemented. However, document (1) in suggesting that the night guard should completely cover all the teeth in the arch while leaving the palate and as much contiguous gingival tissue as possible uncovered, contained a clear indication to adjust the configuration of the tray to such an extent that the patient no longer feels any discomfort. The dentist confronted with an oversensitive patient wearing a

document (1) tray would therefore progressively adjust and cut back the tray with a handpiece as described in this document and thus arrive at a configuration leaving all the tissues except the teeth surfaces free from tray material. In these circumstances, any contact with the gum being avoided, there is no longer any prejudice against the use of the teaching of document (2) as raised by the Appellant. Taking into account the very vague and broad technical meaning of relative terms such as "trimmed barely shy" (which means, according to the Appellant's submissions, the same as "just short of") and "scalloped up and around interdental papilla" so that the finished tray does not cover the papilla, the configuration resulting from such a progressive adjustment of a document (1) tray could not be distinguished from the tray configuration described in claim 16. To achieve this result would require no more than the normal professional skill of a dentist and could not amount to an inventive step.

- 7.4.6 The same reasoning applies to the "thickness" argument raised by the Appellant. Document (1) clearly refers to a vacuum formed soft plastic nightguard approximately 2 mm thick. It must be clear that faced with a problem of discomfort resulting from the thickness of the tray material, the dentist would try to form the nightguard as thin as possible and that this would depend on the characteristics of the material used. The thickness of the material is limited by the stability of the form or shape of the tray. In the case of a soft plastic material as described in document (1), the thickness and flexibility of the material are directly correlated properties.

Accordingly, claim 16 of the sixth auxiliary request

does not fulfill the requirements of Article 56 EPC with respect to inventive step.

8. Since each of the Appellant's requests fails to meet the requirements of the EPC, there is no reason to set aside the decision of the first instance.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

P. A. M. Lançon