PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
508286/128104MJ		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/BE00/00107	14/09/2000	14/09/2000
International Patent Classification (IPC) or national classification and IPC A61K7/20		
Applicant HIGH TECH LASER et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07/03/2002	31.10.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Szarek, S Telephone No. +49 89 2399 8219

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/BE00/00107

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-14 as originally filed

Claims, No.:

1-14 as received on 03/10/2002 with letter of 03/10/2002

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1, 10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 10
Industrial applicability (IA)	Yes:	Claims	10-14
	No:	Claims	

2. Citations and explanations
see separate sheet

I

1. The amendments filed with the letter dated 03.10.2002 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

   Claim 1
   Amended claim 1 is based on claims 1, 2 and 9 as originally filed.
   However, the technical feature : "characterised in that to manufacture the medicament, the composition is irradiated with laser emitting electromagnetic irradiation.." is not disclosed in the application as originally filed. In the application as filed it is disclosed that the composition is irradiated with laser emitting electromagnetic irradiation once it has been applied to teeth that have to be bleached.
   Moreover, the first part of the claim is directed to the use of a composition for manufacturing a medicament for dental bleaching whereas the characterising part is directed to the process of manufacture of the medicament. Therefore, the claim contains inconsistencies and is not clear (Article 6).

   Claim 8
   No basis in the application as filed can be found for the technical feature "preferably 35-50% by weight of a peroxide" (see page 7, l.30 of the application as originally filed).

Therefore, this report has been established on the original claims 1-8 as filed and on claims 10 to 14 as filed with the letter dated 03.10.2002 (Rule 70.2(c) PCT).

III

Claims 1-8 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

V

Reference is made to the following documents :

D1 : WO 97/21420
D2 : WO 98/23219

1. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1 and 10 is not new.

1.1 Claim 1

Claim 1 is directed to a method of bleaching teeth, the method comprising the steps of coating an area of at least one teeth to be bleached with a dental bleaching composition and irradiating the coated area with laser energy for a predetermined period of time to activate an oxidising agent being capable of reacting with the staining agent to at least partly discolour the staining agent, characterised in that use is made of a laser emitting laser energy of a wave length capable of inducing a photochemical generation of radicals of the oxidising agent, which radicals in turn are capable of reacting with the staining agent to form a compound that is free of a conjugated electron system capable of absorbing visible light.

Such a method is disclosed in :

D1 : Page 4, lines 2 to 20; Page 6, line 4 to page 9, line 7; Page 10, line 1 to page 11, line 11; Page 11, line 18 to page 12, line 5; Claims 1 to 11.

D2 : Page 3, lines 24 to 35; Page 4, line 24 to page 5, line 23; Page 7, lines 21 to 37; Page 8, lines 22 to 36; Page 10, lines 22 to 31; Claims 1, 15 to 20, 23 to 27, 30, 40 to 42, 45 to 49, 53 to 55.

The subject-matter of claim 1 is therefore not new.

1.2 Claim 10

The topical dental bleaching composition as defined in the claim is disclosed in :

D1 : Page 4, lines 2 to 20; Page 7, lines 1 to 5 : the argon laser with a wavelength in the range of 450-530 nanometers falls within the claimed range which is 525-545 nm. Page 8 : table I, last line; Page 9, lines 1 to 7; Page 10, line 1 to page 11, line 11; Page 11, line 18 to page 12, line 5; Claims 1 to 11.

D2 : Page 3, lines 24 to 35; Page 4, line 24 to page 5, line 23; Page 7, lines 21 to 37; Page 8, lines 22 to 36; Page 10, lines 22 to 31; Claims 1, 15 to 20, 23 to 27, 30, 40 to 42, 45 to 49, 53 to 55.
The compositions disclosed in D1 and D2 being identical to the composition defined in claim 10, the subject-matter of claim 10 is not new.

2. For the assessment of the present claims 1 to 8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3. Claims 11, 12, 13 and 14 : The dependencies should be corrected.
Claim 11 : the claim contains twice the technical feature "more preferably 38-42 wt%".

AMENDED SET OF CLAIMS

1. Use of a composition for manufacturing a medicament for dental bleaching, the composition containing an oxidising agent capable of interacting with a staining agent present in teeth, a pH adjusting compound, a thickening agent and a laser absorption enhancing compound, the oxidising agent being a compound capable of generating radicals upon irradiation by the laser, characterised in that to manufacture the medicament the composition is irradiated with a laser emitting electromagnetic irradiation having a wavelength of approximately 525-545 nm so as to induce a photochemical reaction to the oxidising agent to form radicals reactive with the staining agent and to form a compound that is free of a conjugated electron system capable of absorbing visible light.

2. Use of a composition for manufacturing a medicament for dental bleaching as claimed in claim 1, characterised in that a laser is used emitting laser energy with a wave length of approximately 532 nm.

3. Use of a composition for manufacturing a medicament for dental bleaching as claimed in claim 1 or 2, characterised in that use is made of a dental bleaching composition containing an absorbing agent with a colour substantially complementary to the laser light.

4. Use of a composition for manufacturing a medicament for dental bleaching as claimed in any one of claims 1-3, characterised in that use is made of a dental bleaching composition containing a thickening agent with a mean particle size from about 50 micron to 400 micron, preferably from about 75 microns to 200 microns, more preferably from about 90 microns to 125 microns.

5. Use of a composition for manufacturing a medicament for dental bleaching as claimed in any one of claims 1-4, characterised in that use is made of a dental bleaching composition containing an oxidising agent selected from the group of peroxides, perborates and oxalic acid.

6. Use of a composition for manufacturing a medicament for dental bleaching as claimed in any one of claims 1-5, characterised in that use is made of a dental bleaching composition containing Rhodamine as an absorbing agent.

7. Use of a composition for manufacturing a medicament for dental bleaching as claimed claim 6, characterised in that rhodamine is present in a concentration of 0.25-1 % by weight with respect to the total weight of the composition.

8. Use of a composition for manufacturing a medicament for dental bleaching as claimed in any one of claims 1-7, characterised in that use is made of a dental bleaching composition containing 30-80 wt %, preferably 35-50 wt% 38-42 % by weight of a peroxide compound as an oxidising agent.

9. Use of a composition for manufacturing a medicament for dental bleaching as claimed in any one of claims 1-8, characterised in that a dental bleaching composition is used with a pH of between 8.5-10.5, preferably 9-9.5.

10. A topical dental bleaching composition containing an oxidising agent capable of interacting with a staining agent present in teeth, a pH adjusting compound, a thickening agent and a laser absorption enhancing compound, characterised in that the oxidising agent is a compound capable of generating radicals upon irradiation with electromagnetic irradiation with a wave length of approximately 525-545 nm **through photochemical reaction**, the oxidising agent **radicals** being capable of reacting with the staining agent to form a compound that is free of a conjugated electron system capable of absorbing visible light.

11. A topical dental bleaching composition as claimed in claim 11, characterised in that the composition contains 30-50 wt. %, preferably 38-42 wt. %, more preferably 38-42 wt% of an oxidising agent.

12. A topical dental bleaching composition as claimed in claim 11 or 12, characterised in that the composition contains an absorbing agent capable of absorbing energy with a wave length of 525-545 nm.

13. A topical dental bleaching composition as claimed in any one of claims 11 - 13, characterised in that the composition contains a colourant selected from the group of Rhodamine ®, acid Fuchsin, Alizarin Red, Basic Fuchsin, Carmine, Congo Red, Darrow Red, Oil Red O, Methyl Orange, Natural Red, Orange, Methyl Red, Chlorphenol Red, Phenol Red.

14. A topical dental bleaching composition as claimed in any one of claims 11 - 14, characterised in that the composition has a pH of between 8.5-10.5, preferably 9-9.5.