Title: GROWTH FACTOR ENCAPSULATION SYSTEM FOR ENHANCING BONE FORMATION

Abstract: This invention provides articles of manufacture, compositions of matter and methods related to a growth factor encapsulation system for enhancing bone formation.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC: A61P 2/00(2007.01); A61K 9/48(2007.01); A01N 63/00(2007.01)
USPC: 424/93.72, 423, 451
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S.: 424/93.72, 423, 451

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPATFUL, CAONLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category *</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 6,747,127 B1 (McCORMICK et al.) 08 June 2004 (08.06.2004), column 1, lines 35-50.</td>
<td>1-12</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,084,350 A (CHANG et al.) 26 January 1992 (26.01.1992), column 4, lines 43-55.</td>
<td>5, 6</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,294,446 A (SCHLAMEUS et al.) 15 March 1994 (15.03.1994) column 4, lines 20-25.</td>
<td>1-12</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other meaning
- "P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search
05 December 2006 (05.12.2006)

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Date of mailing of the international search report
22 FEB 2007

Authorized officer
SANDRA E. SAUCIER
PRIMARY EXAMINER

Telephone No. (571) 273-3201

Form PCT/ISA/210 (second sheet) (April 2005)
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(3)(c) for the following reasons:

1. ☐ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-12

Remark on Protest ☐ The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(2)) (April 2005)
BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-12, drawn to a first composition comprising a capsule of protein-permeable material and PRP.

Group II, claims 13-21, drawn to a second composition comprising a porous bead and PRP and/or a growth factor.

Group III, claims 22-30, drawn to a third composition comprising a capsule of protein-permeable material and a growth factor, a porous bead and a growth factor, a gel having PRP and a bone regeneration-facilitating material.

Group IV, claims 31-41, drawn to a method of making the composition of Group I.

Group V, claims 42, 43, 48, 49, drawn to a method of use of Group I.

Group VI, claims 44, 45, 50, 51, drawn to a method of use of Group II.

Group VII, claims 46, 47, drawn to a method of use of Group III.

Group VIII, claims 52-61, drawn to a fourth composition comprising packing material, calcium, a protein-permeable capsule forming material.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or
(2) a product and a process of use of said product; or
(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) a process and an apparatus or means specifically designed for carrying out said process; or
(5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
The groups of invention I, IV, V fall within category (3), a product and a method of use of that product and a method of making that product.

In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of use of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

US 2003/0152639 teach a composition comprising PRP encapsulated in a calcium alginate matrix, example 1. Thus, the composition of Group I cannot be a special technical feature.

Thus, the inventions listed as Groups I, IV, V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as demonstrated above. Since the composition AS CLAIMED is known in the art, no special technical feature unites these inventions in a category.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

PCT Rule 13.2 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use and method of making and the additional compositions and method claims each constitute a separate group.