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(54) Title: HEPAROSAN-BASED BIOMATERIALS AND COATINGS AND METHODS OF PRODUCTION AND USE THEREOF

(57) Abstract: The presently claimed and disclosed invention relates to biomaterial compositions that include an isolated heparosan polymer. The presently claimed and disclosed invention also relates to kits containing such biomaterial compositions, as well as to methods of producing such biomaterial compositions. The presently claimed and disclosed invention further relates to methods of using such biomaterial compositions as surface coatings for implants as well as for augmenting tissues.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/04190

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 31/727; C08B 37/10 (2008.04) USPC - 514/56; 536/21 According to International Patent Classification (IPC) or to both national classification and IPC</p>																	
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) IPC(8): A61K 31/727; C08B 37/10 (2008.04) USPC: 514/56; 536/21</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 435/85; 514/53; 514/54; 514/56; 536/21</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WEST (PGPB,USPT,EPAB,JPAB): heparosan, hyaluronidase, susceptible, degradation, biomaterial, silica, metal, glass, polymer, substrate, non-covalent, covalent ; esp@cenet: heparosan, deangelis Google Scholar: heparosan not susceptible to hyaluronidase</p>																	
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <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>X — Y</td> <td>US 6,444,447 B1 (DEANGELIS) 3 September 2002 (03.09.2002), abstract; col 5, ln 57-60; col 12, ln 54; col 14, ln 47-51; col 16, ln 10-11; col 20, ln 3-11; col 20, ln 4-9; col 23, ln 14-16; col 25, ln 4-8; col 27, ln 4-9; col 30, ln 20-30; col 30, ln 25; col 30, ln 26-29; col 31, ln 1-5; col 32, ln 1-14; col 45, ln 60; col 45, ln 63.</td> <td>1, 4, 6, 8, 10, 12, 13, 16, 20, 23, 24, 26, 27, 31-33, 36, 39 and 72 ----- 2, 3, 5, 7, 9, 11, 14, 15, 17-19, 21, 22, 25, 28-30, 34, 35, 37, 38</td> </tr> <tr> <td>Y</td> <td>US 2004/0197868 A1 (DEANGELIS) 7 October 2004 (07.10.2004), para [0006], [0010], [0076].</td> <td>2, 3, 5, 7, 9, 14, 18, 19, 21, 25, 28-30 and 34</td> </tr> <tr> <td>Y</td> <td>US 2006/0172967 A1 (TOIDA) 3 August 2006 (03.08.2006), abstract; para [0041], [0060].</td> <td>11, 22, 38</td> </tr> <tr> <td>Y</td> <td>US 2006/0188966 A1 (DEANGELIS) 24 August 2006 (24.08.2006), abstract; para [0170], [0171], [0410].</td> <td>15, 17, 35, 37</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X — Y	US 6,444,447 B1 (DEANGELIS) 3 September 2002 (03.09.2002), abstract; col 5, ln 57-60; col 12, ln 54; col 14, ln 47-51; col 16, ln 10-11; col 20, ln 3-11; col 20, ln 4-9; col 23, ln 14-16; col 25, ln 4-8; col 27, ln 4-9; col 30, ln 20-30; col 30, ln 25; col 30, ln 26-29; col 31, ln 1-5; col 32, ln 1-14; col 45, ln 60; col 45, ln 63.	1, 4, 6, 8, 10, 12, 13, 16, 20, 23, 24, 26, 27, 31-33, 36, 39 and 72 ----- 2, 3, 5, 7, 9, 11, 14, 15, 17-19, 21, 22, 25, 28-30, 34, 35, 37, 38	Y	US 2004/0197868 A1 (DEANGELIS) 7 October 2004 (07.10.2004), para [0006], [0010], [0076].	2, 3, 5, 7, 9, 14, 18, 19, 21, 25, 28-30 and 34	Y	US 2006/0172967 A1 (TOIDA) 3 August 2006 (03.08.2006), abstract; para [0041], [0060].	11, 22, 38	Y	US 2006/0188966 A1 (DEANGELIS) 24 August 2006 (24.08.2006), abstract; para [0170], [0171], [0410].	15, 17, 35, 37
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<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/></p>																	
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"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)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"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)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed						
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<p>Date of the actual completion of the international search 7 March 2009 (07.03.2009)</p>		<p>Date of mailing of the international search report 24 MAR 2009</p>															
<p>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</p>		<p>Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>															

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/04190

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(2)(a) 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:

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 1-39 and 72 are directed to either a biomaterial composition comprising an isolated heparosan polymer or a kit for in vivo administration of such a biomaterial composition, or a method comprising administering such a biomaterial composition for administration to a mammalian patient.

Group II: Claims 40-72 are directed to either a method for providing a coating on a surface of a synthetic implant, a method of augmenting tissue in a patient, or a method comprising administering a biomaterial composition for administration to a mammalian patient.

--- Please see continuation on attached 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 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.:
1-39 and 72

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/04190

Continuation of Box (III) - Lack of Unity:

The groups listed above 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.

The technical feature that links the listed Groups is a biomaterial composition comprising an isolated heparosan polymer, wherein the isolated heparosan polymer is biocompatible with a mammalian patient and is represented by the structure $(-\text{GlcUA}-\beta\text{1,4}-\text{GlcNAc}-\alpha\text{1,4-})_n$, wherein n is a positive integer greater than or equal to 1. However, this does not represent an improvement over the prior art of US 6,444,447 B1 to DeAngelis which teaches such a polymer (col 20, ln 3-11 and the abstract). Although claim 72 is grouped with similar methods of using the heparosan polymer in Group II, the claim has also been included in Group I because it reads on the prior art of record.

Accordingly, unity of invention is lacking under PCT Rule 13.2 because the groups do not share a same or corresponding special technical feature providing a contribution over the prior art.