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21 January 2010

(54) Title: THERAPEUTIC USES OF BIOCOMPATIBLE BIOGEL COMPOSITIONS

(57) Abstract: The present invention relates to biocompatible biogel compositions and methods of drug delivery. The biocompatible biogel is a physical polymer matrix formed via affinity interactions between its components. The components of the biocompatible biogel comprise a cationic component, an anionic component, and optionally a therapeutic agent.



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 9/14 (2009.01)

USPC - 424/486

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)

IPC(8) - A61K 9/14 (2009.01)

USPC - 424/486

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
424/487 424/78.06 424/78.07

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

PubWest (PGPB,USPT,USOC,EPAB,JPAB) Google scholar: hydrogel, biogel, gel, matrix, network, hydrophilic, scaffold, inflammation, inflamm\$, chondrocyte, myocyte, osteoblast, acrylamide, styrene, acrylic acid, heal, healing, wound, lesion, differentiable, differentiate, differentiating, differentiation, multipotent. GenCore 6.3: SEQ ID NO:1-2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2003/0190364 A1 (PANITCH et al.) 09 October 2003 (09.10.2003) para [0023]; [0033]-[0034]; [0038]; [0052]-[0055]; [0060]-[0061]; [0063]-[0064]; [0076]; [0095]-[0097]	1-2, 6, 57-58, 62 ----- 3-5, 7-9, 12-22, 39-48, 51-56, 59-61, 63-65, 68-75
X ----- Y	US 2007/0026518 A1 (HEALY et al.) 01 February 2007 (01.02.2007) para [0009]; [0011]; [0016]-[0019]; [0027]; [0029]; [0037]; [0046]; [0056]; [0058]; [0072]-[0073]; [0075]; [0077]; [0093]; [0159]-[0160]; [0178]; [0208]; [0212]-[0216]; [0243]-[0245]; [0253]; [0257]; [0274]; [0287]; Fig 6	23-31, 33, 36-38 ----- 32, 34-35
X	US 2003/0134810 A1 (SPRINGATE et al.) 17 July 2003 (17.07.2003) para [0006]; [0015]; [0028]; [0051]; [0085]; abstract	76
Y	US 2008/0038352 A1 (SIMPSON et al.) 14 February 2008 (14.02.2008) para [0009]; [0011]; [0076]; [0098]; [0107]; [0118]; [0139]; [0220]	3-5, 39-48, 51-56, 59-61
Y	US 5,415,864 A (KOPECEK et al.) 16 May 1995 (16.05.1995) col 3, ln 55 - col 4, ln 20; col 5, ln 59 - col 6, ln 2; col 6, ln 34-54	12-17, 34-35, 51-56, 68-73
Y	US 2007/0154448 A1 (REID et al.) 05 July 2007 (05.07.2007) para [0011]; [0013]; [0016]; [0075]-[0076]; abstract	18-22, 32
Y	US 2007/0202189 A1 (AHLFORS) 30 August 2007 (30.08.2007) para [0005]-[0007]; [0066]; [0091]-[0092]	74-75



Further documents are listed in the continuation of Box C.



* 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 but 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 means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&"

document member of the same patent family

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0041899 A1 (CHUDZIK et al.) 11 April 2002 (11.04.2002) para [0031]; [0033]; [0087]	13-14, 34-35, 52-53, 69-70
Y	US 2002/0009491 A1 (ROTHBARD et al.) 24 January 2002 (24.01.2002) para [0012]-[0014]; [0032]; abstract	15-17, 54-56, 71-73
Y	US 7,041,814 B1 (WEINSTOCK et al.) 09 May 2006 (09.05.2006) col 2, ln 48-64; col 9, ln 14-53; col 10, ln 50-59; col 11, ln 50-56; SEQ ID NO: 9714, nucleotides 232-240	7-9, 46-48, 63-65
A	US 2003/0187232 A1 (HUBBELL et al.) 02 October 2003 (02.10.2003) para [0001]; [0017]; SEQ ID NO: 10	10-11, 49-50, 66-67

***** Supplemental Box *****

Continuation of Box No III: Observations where unity of invention is lacking:

The inventions listed as Groups I-II 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:

Group I does not include the inventive concept of a peptide of Formula I, as required by Group II.

Groups I and II share the technical feature of treating a wound with a biocompatible biogel composition. However, this shared technical feature does not represent a contribution over the prior art of US 2003/0134810 A1 to Springate et al. that teaches the claimed biogel and a method of using it for treating wounds (abstract):

(a) providing a biocompatible biogel (abstract), comprising

(i) a cationic component; wherein the cationic component comprises a hydrophilic polymer having a molecular weight great than about 3000 g/mole, but less than about 10,000,000 g/mole, to which at least about 3, but no more than 1,000,000 cationic oligomers is grafted (para [0006] and [0028] - 'pegylated chitosan commercially available in a range of molecular weights' includes the claimed molecular weight);

(b) an anionic component (para [0051]); and

(c) a therapeutically effective amount of a therapeutic agent (para [0051] and [0015]);

(ii) administering the biocompatible biogel composition of step (i) to a region of interest within a subject in need thereof, wherein the region of interest contains or is adjacent to an area of inflammation; thereby reducing the inflammation (para [0095]-[0098], [0149] and [0154]-[0156]); and

(b) forming a biocompatible matrix to support wound healing (abstract, para [0055] and [0155]). As the above biogel and the method of using it were known at the time of the invention, this technical feature is not a special technical feature that would otherwise unify the groups.

Groups I and II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing filed or furnished:

a. (means)

☐

on paper

☒

in electronic form

b. (time)

☐

in the international application as filed

☒

together with the international application in electronic form

☐

subsequently to this Authority for the purposes of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

GenCore 6.3: SEQ ID NO:1-2

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/02117

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 1-5, 23-44, 51-61, 68-76, drawn to a method and device for treating a wound with a biocompatible biogel, comprising a therapeutic agent, wherein the therapeutic agent is not a peptide of Formula I.

Group II: claims 1-2, 6-22, 39-40, 43-58, 62-76, drawn to a method and device for treating a wound with a biocompatible biogel, comprising a therapeutic agent, wherein the therapeutic agent is a peptide of Formula I.

***** See sSupplemental Box to continue *****

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.:

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.