

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference B08793A - JAZ	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IB2011/003323	International filing date (<i>day/month/year</i>) 29/12/2011	(Earliest) Priority Date (<i>day/month/year</i>) 29/12/2010
Applicant MEDINCELL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
- ☐ as suggested by the applicant
- ☐ as selected by this Authority, because the applicant failed to suggest a figure
- ☐ as selected by this Authority, because this figure better characterizes the invention
- b. ☒ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2011/003323

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/08 A61K47/34
ADD.

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)

A61L A61K

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/112170 A1 (HOSSAINY SYED F [US] ET AL) 26 May 2005 (2005-05-26) claims 23-25 paragraphs [0049] - [0065] -----	1-30
A	US 5 221 534 A (DESLAURIERS PAUL J [US] ET AL) 22 June 1993 (1993-06-22) column 2, lines 9-17 -----	1-30
A	US 6 592 899 B2 (FOWERS KIRK DEE [US] ET AL) 15 July 2003 (2003-07-15) cited in the application the whole document -----	1-30
A	US 6 350 812 B1 (VERT MICHEL [FR] ET AL) 26 February 2002 (2002-02-26) cited in the application the whole document ----- -/-	1-30



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 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

Date of the actual completion of the international search

2 August 2012

Date of mailing of the international search report

09/08/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Siebum, Bastiaan

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2011/003323

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>SUMING LI: "Bioresorbable Hydrogels Prepared Through Stereocomplexation between Poly(L-lactide) and Poly(D-lactide) Blocks Attached to Poly(ethylene glycol)", MACROMOLECULAR BIOSCIENCE, vol. 3, no. 11, 1 November 2003 (2003-11-01), pages 657-661, XP55034429, ISSN: 1616-5187, DOI: 10.1002/mabi.200350032 the whole document -----</p>	1-30

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2011/003323

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005112170	A1	26-05-2005	AT 389423 T 15-04-2008
		DE 602004012597 T2 16-04-2009	
		EP 1689462 A1 16-08-2006	
		EP 1932551 A1 18-06-2008	
		JP 2007512094 A 17-05-2007	
		US 2005112170 A1 26-05-2005	
		WO 2005051449 A1 09-06-2005	

US 5221534	A	22-06-1993	AT 198703 T 15-02-2001
		CA 2128423 A1 09-06-1994	
		DE 626855 T1 03-08-1995	
		DE 69231649 D1 22-02-2001	
		DE 69231649 T2 03-05-2001	
		EP 0626855 A1 07-12-1994	
		ES 2071598 T1 01-07-1995	
		GR 95300037 T1 30-06-1995	
		JP 2921986 B2 19-07-1999	
		JP H07504441 A 18-05-1995	
		US 5221534 A 22-06-1993	
		WO 9412190 A1 09-06-1994	

US 6592899	B2	15-07-2003	TW 592726 B 21-06-2004
		US 2003068377 A1 10-04-2003	
		WO 03028589 A1 10-04-2003	

US 6350812	B1	26-02-2002	AT 202373 T 15-07-2001
		DE 69613481 D1 26-07-2001	
		DE 69613481 T2 25-04-2002	
		DK 0863933 T3 24-09-2001	
		EP 0863933 A1 16-09-1998	
		ES 2159767 T3 16-10-2001	
		FR 2741628 A1 30-05-1997	
		GR 3036586 T3 31-12-2001	
		JP 4521067 B2 11-08-2010	
		JP 2000500803 A 25-01-2000	
		JP 2008056935 A 13-03-2008	
		PT 863933 E 28-12-2001	
		US 6350812 B1 26-02-2002	
		WO 9719973 A1 05-06-1997	

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

Ernest Gutmann...
ERNEST GUTMANN - YVES PLASSERAUD SAS
3, rue Auber
F-75009 Paris
FRANCE

RECU LE
9 - AOÛT 2012
ERNEST GUTMANN - YVES PLASSERAUD SAS

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference
B08793A-JAZ

Date of mailing
(day/month/year)

9 August 2012 (09-08-2012)

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/IB2011/003323

International filing date
(day/month/year)

29 December 2011 (29-12-2011)

Applicant

MEDINCELL

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see PCT Applicant's Guide, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide, National Chapters*.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference B08793A - JAZ	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IB2011/003323	International filing date (<i>day/month/year</i>) 29/12/2011	(Earliest) Priority Date (<i>day/month/year</i>) 29/12/2010
Applicant MEDINCELL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6**bis**(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

- ☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention

b. ☒ none of the figures is to be published with the abstract

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/B2011/003323

International filing date (day/month/year)
29.12.2011

Priority date (day/month/year)
29.12.2010

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/08 A61K47/34

Applicant
MEDINCELL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Siebum, Bastiaan

Telephone No. +31 70 340-0



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2011/003323

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established 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
4. ☐ 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.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-30</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-30</u>
Industrial applicability (IA)	Yes: Claims	<u>1-30</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2011/003323

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reference is made to the following documents:

- D1 US 2005/112170 A1 (2005-05-26)
- D2 US 5 221 534 A (1993-06-22)
- D3 US 6 592 899 B2 (2003-07-15) cited in the application
- D4 US 6 350 812 B1 (2002-02-26) cited in the application
- D5 Suming Li, Macromol. Biosci. v.3 (2003) n.11, p. 657-661.

1 Novelty

The subject-matter of claims 1-30 is new in the sense of Article 33(2) PCT.

- 1.1 Document D1 discloses biodegradable drug delivery compositions comprising a diblock copolymer, triblock copolymer or blend of di- and triblock copolymers both comprising a PEG block of 500-30000 Da and a poly(lactic acid) block of 1500-7500 Da (D1: cl.23-25 and par.[0049]-[0065]). The diblock PEG will be endcapped however D1 does not disclose the ratio of the ABA to CA polymers.
- 1.2 Document D2 discloses blends of di- and tri-block copolymers, showing thermoreversible gelling, for health and beauty applications (D2: col.2 l.9-17). Though the cremes do comprise an active principle, the polymers of D2 are of the styrene-butadiene type (SB/SEBS) and do not comprise a polyester and polyethylene glycol and are thus also not biodegradable.
- 1.3 Document D3 discloses biodegradable drug delivery compositions comprising a polyester-PEG-polyester triblock copolymer or a mPEG-polyester diblock copolymer. D3 does not disclose a blend of these block copolymers.
- 1.4 Document D4 discloses polyester-PEG-polyester triblock copolymers in a water miscible organic solvent such as DMSO for drug delivery, however, D4 does not disclose a blend with a diblock copolymer.

- 1.5 Document D5 discloses biodegradable drug delivery compositions comprising a polyester-PEG-polyester triblock copolymer or a mPEG-polyester diblock copolymer. Only the triblock copolymers formed a blend through stereocomplexation, however, a gel with a blend of di- and tri-block copolymers is not disclosed.

2 Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-30 does not involve an inventive step in the sense of Article 33(3) PCT.

- 2.1 Document D1 is considered the closest prior-art.
- 2.2 The difference between claim 1 and D1 is the ratio of di- to tri-block copolymers being between 3:2 to 1:19.
- 2.3 According to the description the problem is to provide an injectable solidifying composition having an increased lifespan and long acting drug release having a reduced initial burst (p.2 l.15-16).
- 2.4 The results provides in the current application show that no all ratio's between 3:2 and 1:19 shown slower and long acting drug release (figures). Additionally, there is no data regarding lifespan and solidifying properties, wherein the latter only applies for some embodiments and not in general since the composition can also be used a solid.
- 2.5 Since the effect is not achieved over the whole range claimed, the problem is reformulated less ambitiously as to provide an alternative biodegradable drug delivery composition comprising di- and tri-block copolymers of polyesters and PEG.
- 2.6 The skilled person would, without special effect, optimized the ratio depending on the drug to be delivered as routine work. Thus, the subject-matter of claim 1 cannot be considered inventive.
- 2.7 The dependent claims do not provide technical features that would provide an inventive step.

3 Industrial applicability

The subject-matter of claims 1-30 is considered to be industrial applicable and is therefore considered to satisfy the criteria set forth in Article 33(4) PCT.

Re Item VIII

- 1 Claims 2, 13 and 14 comprise all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).
- 2 Claim 26 comprise all the features of claim 25 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).