(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 June 2009 (11.06.2009)

PCT

(10) International Publication Number
WO 2009/073192 A3

(51) International Patent Classification:
A61K 9/16 (2006.01) *A61P 25/18* (2006.01)
A61K 31/196 (2006.01) *A61P 29/00* (2006.01)
A61K 31/519 (2006.01)

(21) International Application Number:
PCT/US2008/013335

(22) International Filing Date:
3 December 2008 (03.12.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/005,400	4 December 2007 (04.12.2007)	US
11/999,415	4 December 2007 (04.12.2007)	US
61/131,123	4 June 2008 (04.06.2008)	US
61/131,716	10 June 2008 (10.06.2008)	US

(71) Applicant *(for all designated States except US)*: **LANDEC CORPORATION** [US/US]; 3603 Haven Avenue, Menlo Park, CA 94025 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **TAFT, David, D.** [US/US]; 3603 Haven Avenue, Menlo Park, CA 94025 (US). **BITLER, Steven, P.** [US/US]; 3603 Haven Avenue, Menlo Park, CA 9405 (US). **ZHENG, Qiang** [US/US]; 3603 Haven Avenue, Menlo Park, CA 94025 (US). **TZANNIS, Stelios, T.** [GR/US]; 3603 Haven Avenue, Menlo, CA 94025 (US). **BELL, Adam, W** [GB/US]; 58 West Portal Avenue # 121, CA 94127 (US). **DAI, Weiguo** [US/US]; 1032 Merritt Terrace, Sunnyvale, CA 94086 (US). **OTTENSMANN, Sandra, N** [US/US]; 487 Ortega Avenue # 7, Mountain View, CA 94040 (US). **BALACHANDER, Natarajan** [US/US]; 2223 Borolink Drive, West Lafayette, IN 47906 (US).

(74) Agents: **KASER, Matthew** et al.; Bell & Associates, 58 West Portal Avenue, # 121, San Francisco, CA 94127 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
22 October 2009

(54) Title: SYSTEMS AND METHODS FOR DELIVERY OF MATERIALS

(57) Abstract: Systems and methods for delivering release materials, for example drugs and other bioactive materials. Crystalline polymeric systems, referred to as CYC carriers, are associated with the release materials, through chemical bonding or through physical association. The crystallinity of the CYC carriers results from the presence of crystallizable side chains, for example long chain n-alkyl moieties, which results in relatively low and sharp melting temperatures. One class of CYC carriers, referred to as CYSC polymers, have a majority of the crystallizable side chains pendant from the polymer backbone. Another class of CYC carriers, referred to as ECC polymers, have a majority of the crystallizable side chains attached to terminal units of the polymer backbone. The ECC polymers can for example be obtained by modification of PLGA polymers. The CYC carriers in another class of non-polymeric. Some CYC carriers, referred to as CYC assemblies, have enhanced crystallinity as a result of the physical association of crystallizable moieties which are present in different types of molecule, for example between a polymer containing crystallizable moieties and a monomer containing crystallizable moieties. For some uses, particularly the delivery of drugs, a bioerodable CYC carrier is preferably used.

WO 2009/073192 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/013335

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K9/16 A61K31/196 A61K31/519 A61P25/18 A61P29/00

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)
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 practical, search terms used)
EPO-Internal, WPI Data, EMBASE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/19333 A (LANDEC CORP [US]) 22 March 2001 (2001-03-22)	1-3,5, 7-10, 13-15, 18-22, 24-27
X	page 3, line 25 - page 6, line 9 page 7, line 23 - page 10, line 17	16,17,29
X	DE 199 08 753 A1 (JENAPHARM GMBH [DE]) 24 August 2000 (2000-08-24) page 2, line 45 - page 3, line 68	16-22, 24-27,29
X	WO 98/11166 A (LANDEC CORP [US]) 19 March 1998 (1998-03-19)	1-3,5, 7-10, 13-22, 24-27,29

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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	Date of mailing of the international search report
29 May 2009	09/09/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	S. von Eggelkraut-G.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/013335

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 736 125 A (MORAWSKY NATALIE A [GB] ET AL) 7 April 1998 (1998-04-07) column 2, line 37 - column 4, line 54 examples 3,4	
P,X	WO 2008/066657 A (AESTHETIC SCIENCES CORP [US]; SCHMITT EDWARD E [US]; KRUMME JOHN F [US]) 5 June 2008 (2008-06-05) page 12, paragraph 1 - page 16, paragraph 1 claims 1,6,20	1-22, 24-27,29
P,X	WO 2008/070118 A (LANDEC CORP [US]; TAFT DAVID D [US]; BITLER STEVEN P [US]; ZHENG QIANG) 12 June 2008 (2008-06-12) the whole document	1-22, 24-27,29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/013335

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:

see additional sheet

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

2. ☐ As all searchable claims could be searched without effort justifying an 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 reportcovers 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.:

see annex

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 16(part) -22(part), 24(part) -27(part),29

A pharmaceutical formulation which comprises a CYC carrier and a drug associated with the CYC carrier, the CYC carrier being an ECC polymer which (A) comprises a plurality of polymeric molecules which have a backbone which comprises terminal units having the formula Yterm-b?Cy (2) where Yterm is a moiety at the end of the backbone, and
b is a bond or moiety which links the Cy moiety to Yterm, and Cy is a moiety which is associated with other Cy moieties to provide the CYC polymer with crystallinity; the Cy moieties in said terminal units providing at least 50% by weight of
the Cy moieties in the polymeric molecules, and
(B) has a crystalline melting temperature, Tp, of at least 0°C and a heat
of fusion, DeltaH, of at least 3 J/g which result from association of the Cy
moieties, Tp and DeltaH being measured on a differential scanning
calorimeter (DSC).

---

2. claims: 16(part)-22(part),23,24(part) -27(part),28

A release composition which comprises a CYC carrier and a release material associated with the CYC carrier, the CYC carrier being selected from the group consisting of CYC polymers, CYC compounds and CYC assemblies and mixtures of one or more thereof,
a CYC polymer being defined as a polymer which (A) comprises polymeric molecules having a backbone and comprising at least one moiety which (1) has the formula ?b?Cy, and (ii) either (A) forms part of a repeating unit of the backbone, the repeating unit having formula (1) below ? Ych? b?Cy (1) where Y is a moiety forming part of the backbone,
or (B) forms part of a terminal unit of the backbone, the terminal unit having formula (2) below Yterm b?Cy (2) where Yterm, is a moiety at the end of the backbone, and
b and Cy are as defined in formula (1); and (B) has a crystalline melting temperature, Tp, of at least 0°C and a DeltaH of at least 3J/g which results from association of the Cy moieties;

---

3. claims: 16(part)-22(part), 24(part) -27(part)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A release composition which comprises a CYC carrier and a release material associated with the CYC carrier, the CYC carrier being selected from the group consisting of CYC polymers, CYC compounds and CYC assemblies and mixtures of one or more thereof,
a CYC compound being defined as a non-polymeric compound which (A) has the formula
Q (bCy)q (4) wherein q is least 2, e.g. 3-8, Q is a moiety having a valence of at least q,
b is a bond or a moiety linking the Cy moiety to the Q moiety, and Cy is as defined in formula (1), and (B) has a crystalline melting temperature, Tp, of at least 0°C and a DeltaH of at least 3J/g which results from association of the Cy moieties;

---

4. claims: 16(part)-22(part), 24(part) -27(part)

A release composition which comprises a CYC carrier and a release material associated with the CYC carrier, the CYC carrier being selected from the group consisting of CYC polymers, CYC compounds and CYC assemblies and mixtures of one or more thereof,
a CYC assembly being defined as an assembly of (i) a polymer which is a CYC polymer as defined above except that the polymer does not necessarily have a Tp of at least 0°C and a DeltaH of at least 4J/g and (ii) a compound which contains a Cy moiety and which is intimately mixed with the polymer but is not covalently linked to the polymer, the assembly having a crystalline melting temperature, Tp, of at least 0°C and a DeltaH of at least 3J/g which results from association of the Cy moieties.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/013335

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0119333 A	22-03-2001	AT 414503 T	15-12-2008
		EP 1212037 A1	12-06-2002
		EP 2030608 A1	04-03-2009
		JP 2003509539 T	11-03-2003
		US 2005272615 A1	08-12-2005
		US 7101928 B1	05-09-2006
		US 2001018484 A1	30-08-2001
DE 19908753 A1	24-08-2000	AT 217800 T	15-06-2002
		AU 3550100 A	04-09-2000
		CA 2368348 A1	24-08-2000
		WO 0048643 A1	24-08-2000
		DK 1152776 T3	19-08-2002
		EP 1152776 A1	14-11-2001
		ES 2178631 T3	01-01-2003
		JP 3395842 B2	14-04-2003
		JP 2002537418 T	05-11-2002
		PT 1152776 E	31-10-2002
		US 6815469 B1	09-11-2004
WO 9811166 A	19-03-1998	AU 4265297 A	02-04-1998
		EP 0925332 A1	30-06-1999
		JP 2001500187 T	09-01-2001
US 5736125 A	07-04-1998	AU 716399 B2	24-02-2000
		AU 5822998 A	03-08-1998
		BR 9804762 A	25-01-2000
		CA 2248699 A1	16-07-1998
		EP 0893984 A1	03-02-1999
		JP 2000507273 T	13-06-2000
		NO 984147 A	10-11-1998
		WO 9830194 A2	16-07-1998
WO 2008066657 A	05-06-2008	AR 063453 A1	28-01-2009
WO 2008070118 A	12-06-2008	AU 2007328207 A1	12-06-2008
		CA 2670749 A1	12-06-2008
		US 2008269105 A1	30-10-2008
		WO 2008070165 A1	12-06-2008