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(54) **Title:** BLOCK COPOLYMER COMPOSITIONS AND USES THEREOF

(57) **Abstract:** The present invention describes compositions, devices, and methods for the production, use and administration of the composition having a non-thermoreversible block copolymer composition.



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/30715

A. CLASSIFICATION OF SUBJECT MATTER IPC(8): A61K 31/00( 2006.01)  USPC: 424/78.3 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. : 424/78.3, 424/486, 424/426  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) EAST		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y <b>y</b>	US 2004/0185104 A1 (PIAO et al) 23 September 2004 (23.09.2004), abstract, [0003],[0012]-[0015],[0020],[0025],[0028],[0032],[0048]-[0049],[0051],[0054],[0056],[0058], examples and claims.	1-65,69-82,87-1 18
Y /	JACKSON.J.K. The Suppression of Human Prostate Tumor Growth in Mice by Intratumoral Injection of a Slow-Release Polymeric Paste Formulation of Paclitaxel CANCERRES. August 2000, VoI 60. pages 4146-4151, especially abstract and page 4147.	1-65,69-82,87-1 18
Y	US 6,551,610 B2 (SHALABY et al) 22 April 2003 (22.04.2003), col 8 Hn 1-25, col 9 Iin 7-37, examples.	1-65,69-82,87-1 18
Y	US 2006/0045901 (Weber) 2 March 2006 (02.03.2006), abstract, [0052]-[0055],[0073]-[0074],[0088],[0090]	1-65,69-82,87-118
<b>D</b> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		
Date of the actual completion of the international search 27 December 2006 (27.12.2006)	Date of mailing of the international search report <b>26 FEB 2007</b>	
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	Authorized officer <i>James W. Rogers</i> James W. Rogers, Ph.D. Telephone No. (571) 271-0000	

**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.

Group I, claim(s) 1-52,64-71.77-78,83-89 drawn to a method of treating fibrosis at a joint comprising administering to a patient in need thereof a composition comprising a block copolymer, a non-polymeric additive and a fibrosis enhancing agent.

Group II, claim(s) 1,53-63, 72-76.79-82 drawn to a method of treating fibrosis at a joint comprising administering to a patient in need thereof a composition comprising a block copolymer, a non-polymeric additive and a fibrosis enhancing agent as a first phase and the composition further comprises a second phase.

Group III, claim(s) 90-100, drawn to a method of treating arthritis comprising administering to a patient in need thereof a composition comprising a block copolymer, a non-polymeric additive and an anti-inflammatory agent.

Group IV, claim(s) 101-109, drawn to a method of treating or preventing cartilage loss comprising administering to a patient in need thereof a composition comprising a block copolymer, a non-polymeric additive and a fibrosis enhancing agent.

Group V, claim(s) 110-118, drawn to a method of treating prostate cancer comprising administering to a patient in need thereof a composition comprising a block copolymer, a non-polymeric additive and an anti-microtubule agent.

The inventions listed as Groups I-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 for the following reasons: The special technical feature is a method to administer a composition comprising a block copolymer, a non-polymeric additive and a biologically active agent. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case Piao (US 2004/0185104, cited by applicants) teaches mixtures of various triblock polyester polyethylene glycol copolymers which also comprise bioactive agents (paclitaxel) and non-polymeric additives (surfactants) and the methods to administer the composition. See abstract, [0003], [0012]-[0015],[0025],[0028],[0032]-[0033],[0048],[0051], [0056] and [0058], examples and claims.

As a result no special technical features exist among the different groups because the inventions in Groups I-V fail to make a contribution over the prior art with respect to novelty and inventive step. IN conclusion, there is a lack of unity of inventions and therefore restriction for examination purposes as indicated is proper.

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US06/30715

**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:  
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.:

- 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.