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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

Published:

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(54) Title: MANUFACTURE OF LONG TERM DRUG DELIVERY DEVICES WITH POLYURETHANE BASED POLYMERS

(57) Abstract: This invention is related to the use of polyurethane based polymer as a drug delivery device to deliver biologically active compounds at a constant rate for an extended period of time and methods of manufactures thereof. The device is very biocompatible and biostable, and is useful as an implant in patients (humans and animals) for the delivery of appropriate bioactive substances to tissues or organs. The drug delivery device for releasing one or more drugs at controlled rates for an extended period of time to produce local or systemic pharmacological effects comprises: 1. a reservoir, said reservoir comprising; 2. at least one active ingredient; and, optionally, 3. at least one pharmaceutically acceptable carrier; a polyurethane based polymer completely surrounding the reservoir.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/00

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)
IPC 7 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, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 035 891 A (RUNKEL ET AL) 30 July 1991 (1991-07-30) column 5, line 19 - column 6, line 11 column 9, line 50 - column 10, line 31 column 10, line 65 - column 11, line 54 examples claims ----- -/--	1-4,10, 17

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

[X] Patent family members are listed in annex.

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

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Date of the actual completion of the international search	Date of mailing of the international search report
23 September 2005	06/10/2005

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European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Epskamp, S

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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.
X	ZONDERVAN G J ET AL: "DESIGN OF A POLYURETHANE MEMBRANE FOR THE ENCAPSULATION OF ISLETS OF LANGERHANS" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 13, no. 3, January 1992 (1992-01), pages 136-144, XP000258851 ISSN: 0142-9612 abstract page 137, left-hand column, paragraph 2 - paragraph 3 page 137, right-hand column, paragraph 3 - paragraph 4 page 138, left-hand column, paragraph 3 - paragraph 4	1-3,5-9, 12,14,17
X	US 4 469 671 A (ZIMMERMAN ET AL) 4 September 1984 (1984-09-04) column 5, line 18 - line 43 column 11, line 55 - column 12, line 65 claims	1-4,17
X	EP 0 200 224 A (E.I. DU PONT DE NEMOURS AND COMPANY; THE DU PONT MERCK PHARMACEUTICAL) 5 November 1986 (1986-11-05) page 2, line 12 - line 22 page 10, line 29 - page 12, line 28 examples 1-12,17,18; tables claims	1-4,17
X	US 4 207 890 A (MAMAJEK, RONALD C ET AL) 17 June 1980 (1980-06-17) column 2, line 64 - column 3, line 5 column 5, line 1 - line 23 column 7, line 1 - line 38 examples 3-5 claims	1,3,4,17

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/IB2004/002823

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5035891 A	30-07-1991	NONE	
US 4469671 A	04-09-1984	NONE	
EP 0200224 A	05-11-1986	AU 584549 B2	25-05-1989
		AU 5701186 A	06-11-1986
		CA 1284105 C	14-05-1991
		DE 3684354 D1	23-04-1992
		GR 861145 A1	14-08-1986
		IL 78665 A	12-05-1991
		JP 61268615 A	28-11-1986
		NZ 216035 A	26-04-1989
		US 4673565 A	16-06-1987
		ZA 8603314 A	27-01-1988
US 4207890 A	17-06-1980	NONE	