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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



(54) Title: POROUS POLYMERIC PROSTHESES AND METHODS FOR MAKING SAME

(57) Abstract: Porous polymers having a plurality of openings or chambers that are highly convoluted, with each chamber being defined by multiple, thin, flat partitions are produced by a new gel enhanced phase separation techinque. In a preferred embodiment, a second solven t is added to a ploymer solution, the second solvent causing the solution to gel. The gel can then be shaped as needed. Subsequent solvent extraction leaves the porous polymeric body of defined shape. The porous polymers have utility as medical protheses, the porosity permitting ingrowth of neighboring tissue. The present technique also enhances shape-making capability, for example, of bifurcated vascular grafts, which feature a common entrance re gion but two or more exit regions.

Internation Application No PCT/US 02/35848

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61L27/56 A61L27/14 C08J9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{array}{ccc} \text{Minimum documentation searched} & \text{(classification system followed by classification symbols)} \\ IPC & 7 & A61L & C08J \end{array}$

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-In	ternal, WPI Data, PAJ, COMPENDEX, M	MEDLINE, EMBASE, BIOSIS	
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.
X	US 3 553 008 A (REISCHL ARTUR ET 5 January 1971 (1971-01-05) column 1, line 45 -column 2, lin 1; tables 1,2	·	1-25
X	DATABASE WPI Section Ch, Week 197632 Derwent Publications Ltd., Londo Class A25, AN 1976-60950X XP002231746 & JP 51 074058 A (MITSUBISHI RAN , 26 June 1976 (1976-06-26) abstract		1-25
X Furth	er documents are listed in the continuation of box C.	X Patent family members are listed	in annex.
"A" docume consid "E" earlier of filing d "L" docume which in citation "O" docume other n "P" docume later th	nt which may throw doubts on priority claim(s) or s cited to establish the publication date of another or other special reason (as specified) int referring to an oral disclosure, use, exhibition or	 *T* later document published after the interest or priority date and not in conflict with cited to understand the principle or the invention *X* document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the document of particular relevance; the cannot be considered to involve an inventive and involve an inventive and involve an inventive and involve an inventive and involve and inv	the application but sony underlying the laimed invention be considered to current is taken alone laimed invention ventive step when the re other such docurs to a person skilled family
	3 July 2003	1 1, 09, 03	ист героп
Name and m	nalling address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Piljswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Pilling, S	

PCT/US 02/35848 C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT						
Category °		Relevant to claim No.				
X	DATABASE WPI Section Ch, Week 200109 Derwent Publications Ltd., London, GB; Class A18, AN 2001-075349 XP002231747 & JP 2000 319434 A (NITTO DENKO CORP), 21 November 2000 (2000-11-21) abstract	1-25				
X	US 3 492 154 A (EINSTMAN ROBERT V) 27 January 1970 (1970-01-27) column 5, line 23 - line 65	1-25				
X	US 3 527 653 A (GERLACH KLAUS ET AL) 8 September 1970 (1970-09-08) column 5, line 28 - line 56 column 6, line 62 - line 66	1-25				
X	US 5 229 045 A (SOLDANI GIORGIO) 20 July 1993 (1993-07-20) column 4, line 35 -column 6, line 31	1-63				
X	WO 00 55300 A (KOREA INST SCIENCE TECHNOLOGY ;NAM YOON SUNG (KR); PARK TAE GWAN () 21 September 2000 (2000-09-21) page 4, line 27 -page 5, line 8	1-25				
X	DATABASE WPI Section Ch, Week 197547 Derwent Publications Ltd., London, GB; Class A82, AN 1975-77632W XP002249146 & JP 50 042004 A (KURARAY CO LTD), 16 April 1975 (1975-04-16) abstract	1-25				
X	DATABASE WPI Section Ch, Week 198350 Derwent Publications Ltd., London, GB; Class A18, AN 1983-841300 XP002249147 & JP 58 189242 A (TOYO POLYMER KK), 4 November 1983 (1983-11-04) abstract	1- <u>25</u>				
X	EP 0 382 356 A (ICI PLC) 16 August 1990 (1990-08-16) page 3, line 38 -page 4, line 2	1-25				
X	EP 0 396 809 A (A J N COLLAGEN FORSCHUNGS UND) 14 November 1990 (1990-11-14) abstract	26-63				
	-/					

2.15	C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT					
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
Х	EP 0 216 149 A (KANEGAFUCHI CHEMICAL IND) 1 April 1987 (1987-04-01) abstract	26-63				
X	US 4 355 426 A (MACGREGOR DAVID C) 26 October 1982 (1982-10-26) abstract	26-63				
X	WO 96 37165 A (BSI CORP) 28 November 1996 (1996-11-28) page 7, line 30 -page 9, line 2	26-63				
X	US 4 657 544 A (PINCHUK LEONARD) 14 April 1987 (1987-04-14) abstract	26-63				
X	EP 0 308 102 A (UBE INDUSTRIES) 22 March 1989 (1989-03-22) abstract	26-63				

International application No. PCT/US 02/35848

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
2. X Claims Nos.: 26-63 (part) 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: see FURTHER INFORMATION sheet PCT/ISA/210
See FURTHER INFORMATION SHEET FOT/ISA/ZIV
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 II Observations where unity of invention is lacking (Continuation of item 2 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 all searchable claims.
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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.
No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 26-63 (part)

The definition in Claims 26, 44, 53 and 57 of a "gel enhanced phase separation technique" is unclear since the essential steps of this technique are not defined. Thus, it is unclear what restriction this fabrication technique places upon the prostheses defined in these claims. Consequently, Claims 26, 44, 53 and 57 appear to essentially define porous (vascular) prostheses irrespective of the method used to manufacture them.

The initial phase of the search revealed a very large number of documents relevant to the issue of novelty. So many documents were retrieved that it is impossible to determine which parts of the claim(s) may be said to define subject-matter for which protection might legitimately be sought (Article 6 PCT). For these reasons, a meaningful search over the whole breadth of Claims 26 to 63 is impossible. Consequently, the documents cited in respect of Claims 26 to 63 are merely a random sample of the many documents found. It is possible that a further search will be necessary, if and when the essential features of prostheses are clarified.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. Claims: 1-25

processes of producing a porous polymeric body or composite porous polymeric body

2. Claims: 26-63

prostheses comprising a porous polymer

Information on patent family members.

Pa	tent document	.	Publication		Patent family		Publication
	in search report		date		member(s)		date
US	3553008	Α	05-01-1971	AT	272666		10-07-1969
				BE	692116	Α	16-06-1967
				CH	484230		15-01-1970
				DE	1694059		03-06-1971
				FR	1510261		03-04-1968
				GB	1123292		14-08-1968
				JP	49029621		06-08-1974
				NL	6700072		04-07-1967
				SE 	338759 	В 	20-09-1971
JP	51074058	Α	26-06-1976	JP	59009575	B	03-03-1984
JP	2000319434	Α	21-11-2000	NONE			
US 	3492154	Α	27-01-1970	NONE			
US	3527653	Α	08-09-1970	AT	272258		10-07-1969
				BE	698319		16-10-1967
				CH	479760		15-10-1969
				DE	1635690		22-04-1971
				ES	340880		16-06-1968
				FΙ	44220		30-06-1971
				FR	1527491		31-05-1968
				GB	1142666		12-02-1969
				LU	53887		16-08-1967
				NL	6708454		19-12-1967
				NO	128666		27-12-1973
·				SE	327965	B 	07-09-1970
US	5229045	A	20-07-1993	EP	0533262		24-03-1993
				JP	5192388		03-08-1993
				US	5387621	A 	07-02-1995
WO	0055300	A	21-09-2000	KR	2000060718		16-10-2000
				KR	2001046941		15-06-2001
				EP	1165749		02-01-2002
				JP	2002538914		19-11-2002
				WO	0055300	A1	21-09-2000
				US	6586246	B1	01-07-2003
				AU	7160000	Α	17-05-2001
				BR	0005413		07-08-2001
				CA	2326057	A1	16-05-2001
				CN	1297042		30-05-2001
				HU	0004498		28-10-2001
				NZ	508148	Α	31-05-2002
JP	50042004	Α	16-04-1975	NONE			
JP	58189242	Α	04-11-1983	NONE			
EP	0382356	Α	16-08-1990	AT	122921		15-06-1995
				AU	638226		24-06-1993
				AU	4875890		02-08-1990
				BR	9000345		04-12-1990
				CA	2008502		26-07-1990
				DD	301898		30-06-1994
							00 00 1000
				DE DE	69019544 69019544		29-06-1995 02 - 11-1995

Information on patent ramily members

Patent document		Publication		Patent family member(s)	Publication date
cited in search report		date			
EP 0382356	Α		DK	22190 A	27-07-1990
			EΡ	0382356 A2	16-08-1990
			ES	2072973 T3	01-08-1995
			HU	52404 A2	28-07-1990
			ΙĒ	900235 L	26-07-1990
			ĴΡ	3056129 A	11-03-1991
			NO	900359 A	27-07-1990
					07-11-1990
			PT ZA	92979 A 9000558 A	31-10-1990
EP 0396809	Α	14-11-1990	EP	0396809 A1	14-11-1990
EP 0216149	Α	01-04-1987	JP	1737061 C	26-02-1993
			JP	2062264 B	25-12-1990
			JP	62044260 A	26-02-1987
			JΡ	1789695 C	29-09-1993
			JΡ	4071547 B	16-11-1992
			JP	62064361 A	23-03-1987
			DE	3682734 D1	16-01-1992
			ΕP	0216149 A2	01-04-1987
			US	4725273 A	16-02-1988
			DE	3666530 D1	30-11-1989
			EP	0217115 A1	08-04-1987
US 4355426		26-10-1982	CA	1069252 A1	08-01-1980
00 7000720	**	_U 10 170E	CA	1078552 A2	03-06-1980
			DE	2620631 A1	11-11-1976
					03-12-1976
			FR	2310122 A1	
			JP	52001995 A	08-01-1977
			US	4280514 A	28-07-1981
			US	4374669 A	22-02-1983
			US	4459252 A	10-07-1984
			ÜS	4458366 A	10-07-1984
			US	4627836 A	09-12-1986
					25-07-1978
			US	4101984 A	
			US	4934381 A	19-06-1990
			US	4281669 A	04-08-1981
			US	4936317 A	26-06-1990
			CA	1068052 A1	18-12-1979
			CA	1100191 A1	28-04-1981
			CA	1115456 A2	05-01-1982
WO 9637165	Α	28-11-1996	AU	720963 B2	15-06-2000
## 200/ E00	,,	11 1000	AU	5876996 A	11-12-1996
			CA	2222136 A1	28-11-1996
			EP	1018977 A1	19-07-2000
			JP	3318578 B2	26-08-2002
			JP	2001502187 T	20-02-2001
			WO	9637165 A1	28-11-1996
			US	5744515 A	28-04-1998
US 4657544	Α	14-04-1987	EP	0159034 A2	23-10-1985
UU 700/047	п	1. 04 1307	บิร	4759757 A	26-07-1988
				1065143 A	10-03-1989
	Δ	22 - 03-1080	.15		
EP 0308102	A	22-03-1989	JP 10		11_0//_100/
EP 0308102	Α	22-03-1989	JP	1837751 C	11-04-1994
EP 0308102	Α	22-03-1989			11-04-1994 13-08-1993 10-03-1989

Information on patent family members

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0308102	A		JP	1754751 C	23-04-1993
			JP	4050013 B	13-08-1992
			JР	1064650 A	10-03-1989
			JP	1871721 C	06-09-1994
			ĴΡ	5081258 B	12-11-1993
			DE	3871677 D1	09-07-1992
			DE	3871677 T2	21-01-1993
			ĒΡ	0308102 A1	22-03-1989
			ĒΡ	0446965 A2	18-09-1991
			ŪS	4986832 A	22-01-1991