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- (71) Applicant (for all designated States except US): **DENDREON CORPORATION** [US/US]; 3005 First Avenue, Seattle, WA 98121 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **MENDOZA, Christine, B.** [US/US]; 12414 Nonie Terrace, San Diego, CA 92129 (US). **LIDELL, John** [GB/GB]; Avecia Limited, P.O. Box 2, Belasis Avenue, Billingham TS23 1YN (GB). **MOSS, David** [GB/GB]; 3 Great Close, Cawood, Selby, North Yorkshire YO8 0UG (GB).
- (74) Agent: **MEIKLEJOHN, Anita, L.**; Fish & Richardson, P.C., 225 Franklin Street, Boston, MA 02110-2804 (US).
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(54) Title: PROCESS FOR MANUFACTURE OF NEMATODE-EXTRACTED ANTICOAGULANT PROTEIN (NAP)

(57) Abstract: The present invention provides a process for manufacture of purified Nematode-extracted Anticoagulant Proteins (NAPS), wherein the NAP manufactured by the claimed process method is a NAP drug substance that can be formulated as a NAP drug product. The present invention provides NAP drug substances and NAP drug products manufactured by the process disclosed herein. In one embodiment, the present invention provides a process for manufacture of rNAPc2/proline drug substance and rNAPc2/proline drug product, and provides rNAPc2/proline drug substance manufactured by the process disclosed herein.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/15100

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(7) : C12P 21/02; A61K 38/17; C07K 14/435
 US CL : 435/69.1; 514/12; 530/350
 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. : 435/69.1; 514/12; 530/350

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)
 Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,612,198 (BRIERLEY et al.) 18 March 1997 (18.03.1997), see column 12, line 59-column 13, line 36 and Example 4, column 31, line 30-column 40, line 66.	10-14 and 26-29
X	US 5,866,543 (VLASUK et al.) 2 February 1999 (02.02.1999), see entire document, especially Examples 3,4 and 15-17.	1, 4-9 and 36-42
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Y		2,3 and 10-35
Y	US, 6,331,520 B2 (RICHARDSON et al.) 18 December 2001 (18.12.2001), see column 4, lines 39-57.	2, 3, 23-25, 34, 35, 43 and 44
Y	EP 1 184 393 A1 (DEBIOPHARM SA) 06 March 2002 (06.03.2002), see paragraphs 15, 20-23, 24-29, 43 and 47-56.	15-22, 26 and 30-33

Further documents are listed in the continuation of Box C. 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
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"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	

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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. (703) 305-3230
 Authorized officer: Robert A. Wax, Telephone No. (703) 308-1235

INTERNATIONAL SEARCH REPORT

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Continuation of B. FIELDS SEARCHED Item 3:

EAST search terms: expanded bed chromatography, hydrophobic interaction chromatography, protein purification, Pichia pastoris same methanol with ferment\$

STN search terms expanded bed chromatography, hydrophobic interaction chromatography, protein purification