

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
27 December 2002 (27.12.2002)

PCT

(10) International Publication Number
WO 2002/103029 A3

(51) International Patent Classification⁷: **A61K 39/395**,
A61L 2/08, C07K 16/00, G01N 33/577

(74) Agents: **FLESHNER, Mark, L.** et al.; FLESHNER &
KIM, LLP, P.O. Box 221200, Chantilly, VA 20153-1200
(US).

(21) International Application Number:
PCT/US2002/018823

(22) International Filing Date: 13 June 2002 (13.06.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/880,052 14 June 2001 (14.06.2001) US

(71) Applicant (*for all designated States except US*): **CLEAR-
ANT, INC.** [US/US]; 401 Professional Drive, Gaithers-
burg, MD 20879 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **GRIEB, Teri**
[US/US]; 26800 Grace Court, Damascus, MD 20872
(US). **BURGESS, Wilson H.** [US/US]; 12824 Great Oak
Lane, Clifton, VA 20124 (US). **DROHAN, William N.**
[US/US]; 8417 Oakford Drive, Springfield, VA 22152
(US). **FORNG, Ren-Yo** [US/US]; 10224 Windsor View
Drive, Potomac, MD 20854 (US). **MACPHEE, Martin J.**
[US/US]; 9971 Lake Landing Road, Montgomery Village,
MD 20886 (US). **MANN, David M.** [US/US]; 7430
Brenish Drive, Gaithersburg, MD 20878 (US). **MCBAIN,
Anna** [US/US]; 7809 Potters Mill Court, Derwood, MD
20855 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

Published:

— with international search report

(88) Date of publication of the international search report:
18 March 2004

*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: METHODS FOR STERILIZING PREPARATIONS OF MONOCLONAL IMMUNOGLOBULINS

(57) Abstract: Methods are disclosed for sterilizing preparation of monoclonal immunoglobulins to reduce the level of active bio-
logical contaminants such as viruses, bacteria, yeasts, molds, mycoplasmas, prions and parasites.



WO 2002/103029 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/18823

A. CLASSIFICATION OF SUBJECT MATTER												
IPC(7) : A61K 39/395; A61L 2/08; C07K 16/00; G01N 33/577												
US CL : 422/21-23; 424/176.1; 436/548; 530/390.1												
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. : 422/21-23; 424/176.1; 436/548; 530/390.1												
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)												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	US 4,620,908 (VAN DUZER) 04 November 1986(04.11.1986). See column 3, line 43-column 4, line 16; column 5, lines 12-42; column 6, lines 32-43; column 7, lines 47-57.	1, 3, 7, 35, 42-47, 53-58, 61, 71-73, 81-83										
X	US 5,283,034 A (OKRONGLY et al) 01 February 1994(01.02.1994). See column 3, lines 1-38; column 4, lines 8-53; column 5, line 54-column 6, line 43; column 10, line 10-column 11, line 40.	1, 2, 5, 7, 9, 35, 46-50, 53-57, 61-62, 64, 71-74, 80										
Y	US 6,171,549 B1 (KENT) 09 January 2001(09.01.2001). See column 2, lines 23-62; column 9, line 60-column 10, line 31.	1, 4, 7-8, 35, 42-45, 53-58, 61, 71-73, 80										
X	US 6,312,931 B1 (O'DWYER et al) 06 November 2001(06.11.2001). See column 1, lines 5-48; column 3, line 30-column 4, line 21; column 4, lines 38-48; column 6, lines 34-55; column 8, lines 44-63; column 9, lines 24-59; column 15, line 65-column 16, line 21; column 16, lines 42-47.	1, 4, 7-8, 35, 42-45, 53-58, 61, 71-73, 80										
Y	CHIN et al, "Virucidal treatment of blood protein products with UVC radiation", Photochemistry and Photobiology, 1997, Vol. 65, No.3, pages 432-435. See abstract and paragraph spanning pages 432-433.	2, 35, 46-49, 61, 65, 71-73, 76, 80										
X	WO 00/52031 A2 (IDEC PHARMACEUTICALS CORPORATION) 08 September 2000(08.09.2000). See page 8, lines 6-26; page 15, line 1-page 16, line 4.	89										
☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.												
* Special categories of cited documents: <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"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</td> </tr> <tr> <td>"E" earlier application or patent published on or after the international filing date</td> <td>"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</td> </tr> <tr> <td>"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)</td> <td>"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</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"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	"E" earlier application or patent published on or after the international filing date	"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	"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)	"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	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"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											
"E" earlier application or patent published on or after the international filing date	"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											
"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)	"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											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"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		Date of mailing of the international search report										
18 March 2003 (18.03.2003)		27 JUN 2003										
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer Felicia D. Roberts for David A. Saunders, PhD Telephone No. 703-308-0196										

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/18823

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claim Nos.: 96 and 97 (both occurrences)
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:
Claims 96 and 97 are duplicated and their dependency differ.
3. ☐ Claim 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:

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 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.