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**WO 02/060919 A3**

(54) Title: MOLECULES WITH EXTENDED HALF-LIVES, COMPOSITIONS AND USES THEREOF

(57) Abstract: The present invention provides molecules, including IgGs, non-IgG immunoglobulins, proteins and non-protein agents, that have increased *in vivo* half-lives due to the presence of an IgG constant domain, or a portion thereof that binds the FcRn, having one or more amino acid modifications that increase the affinity of the constant domain or fragment for FcRn. Such proteins and molecules with increased half-lives have the advantage that smaller amounts and or less frequent dosing is required in the therapeutic, prophylactic or diagnostic use of such molecules.

**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US01/48432

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7) : C07H 21/04; A61K 48/00		
US CL : 536/23.1; 514/44		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 536/23.1; 514/44		
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)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/43713 A1 (LEXIGEN PHARAMACEUTICALS CORPORATION) 02 September 1999(02.09.1999), see entire document, page 3, lines 5-7 in particular.	1-20, 58 and 86
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"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	
23 October 2002 (23.10.2002)	30 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 <i>Telicia D. Roberts</i> Michael A. Belyavsky Telephone No. 703/308-0196	

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/48432

## 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.:  
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.  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:  
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 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.: 1-20,58 and 86
  
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.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

Group I, claims 1-20, 58, 86 drawn to modified IgG and a pharmaceutical composition.

Group II, claims 21-39, 59 drawn to fusion protein, comprising non-IgG polypeptide and pharmaceutical composition.

Group III, claims 40-57, 60, 71 drawn to a molecule comprising non-protein agent, pharmaceutical composition and a kit.

Group IV, claims 61,62, 72-77, 79-84 drawn to a method of treating , method of preventing a disease and method of vaccinating, comprising administrating modified IgG.

Group V, claims 63, 78 drawn to a method of treating a disease and method of vaccinating comprising administering a fusion protein.

Group VI, claim 64 drawn to a method of treating disease, comprising administrating a molecule.

Group VII, claims 65, 67, 69 drawn to a nucleic acid, encoding modified IgG, host cell and a kit.

Group VIII, claims 66, 68, 70 drawn to a nucleic acid encoding the fusion protein, host cell and a kit.

Group IX, claim 85 drawn to a method of in vivo diagnosis

The inventions listed as Groups I-IX 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 invention of Group I was found to have no special technical feature that defined contribution over the prior art of Gillies et al. (WO 9943713) (see entire document)

Gillies et al. teaches a modified IgG with an enhanced circulating half-life, wherein modification of amino acid at position 331 (page 3, lines 5 -7).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.