

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
27 February 2003 (27.02.2003)

PCT

(10) International Publication Number  
**WO 03/016472 A3**

- (51) International Patent Classification<sup>7</sup>: **C12P 21/06**, C12N 15/09, 15/19, 15/21, C07K 14/555, 14/56, A61K 38/21
- (21) International Application Number: PCT/US02/25691
- (22) International Filing Date: 12 August 2002 (12.08.2002)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/311,866 12 August 2001 (12.08.2001) US
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- (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, UZ, VC, 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, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, 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: 16 October 2003
- 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.*



**WO 03/016472 A3**

(54) Title: HYBRID INTERFERON/INTERFERON TAU PROTEINS, COMPOSITIONS AND METHODS OF USE

(57) Abstract: The present invention relates to hybrid interferon fusion proteins formed of an interferon- $\alpha$  protein where the C-terminal region of the interferon- $\alpha$  protein is replaced by C-terminal region of interferon- $\tau$ . Also described are nucleic acid sequences encoding the interferon fusion proteins, expression vectors containing such sequences, and therapeutic applications of the interferon fusion proteins. The therapeutic applications include antiviral, anticellular proliferation, and anti-inflammatory applications. One advantage of the interferon fusion polypeptides of the present invention is that they have lower cytotoxic side effects when used to treat cells.

INTERNATIONAL SEARCH REPORT

International application No.

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<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7) : C12P 21/06; C12N 15/09, 15/19, 15/21; C07K 14/555, 14/56; A61K 38/21		
US CL : 435/69.1, 69.51,69.7; 424/85.4,85.7,192.1; 514/12, 885; 530/350,351		
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. : 435/69.1, 69.51,69.7; 424/85.4,85.7,192.1; 514/12, 885; 530/350,351		
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		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,174,996 B1 (JOHNSON et al) 16 January 2001 (16.01.2001), entire document	1-16, 22 and 27
Y	HORISBERGER, M. A. et al. Interferon-alpha Hybrids, Pharmac. Ther. 1995, Vol. 66, No.3, pages 507-534, entire document	1-16, 22 and 27
<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	
26 February 2003 (26.02.2003)	24 MAR 2003	
Name and mailing address of the ISA/US	Authorized officer	
Commissioner of Patents and Trademarks	Jegatheesan Seharaseyon	
Box PCT	Telephone No. 703-308-0196	
Washington, D.C. 20231		
Facsimile No. (703)305-3230		

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/25691

## 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.:
  
  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.: 1-16, 22 and part of 27
- 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**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-16, 22 and part of 27, drawn to a special technical feature of an interferon hybrid polypeptide and a method of inhibiting viral replication.

Group II, claim(s) 17-19, drawn to a special technical feature of a nucleic acid, an expression vector containing the nucleic acid, a host cell expressing the polypeptide and a method of making.

Group III, claim(s) 20-21, drawn to a special technical feature of a pharmaceutical composition.

Group IV, claim(s) 23 and part of 27, drawn to a special technical feature of a method of inhibiting the growth of tumor cells.

Group V, claim(s) 24 and part of 27, drawn to a special technical feature of a method of treating an autoimmune disease in a subject.

Group VI, claim(s) 25 and part of 27, drawn to a special technical feature of a method treating chronic inflammation in a subject.

Group VII, claim(s) 26 part of 27, drawn to a special technical feature of a method of treating a disease condition responsive to interferon.

Inventions I- III are compositions and invention IV-VII are methods.

The compositions of Inventions I, II and III are different from each other as they are directed to nonequivalent types of compounds with different chemical characteristics. Invention I is a polypeptide. Invention II is nucleic acid and a cell containing it. Invention III is a pharmaceutical composition. Inventions IV-VII are different from each other as they are directed to nonequivalent methods. Invention IV is a method of inhibiting the growth of tumor cells. Invention V is a method of treating an autoimmune disease in a subject. Invention VI is a method of treating chronic inflammation in a subject. Invention VII is a method of treating a disease condition responsive to interferon. Each of the treatment methods are different because they treat different disease conditions or states.

The claims of these groups are directed to different inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The claims in the different groups lack the same or corresponding special technical features. In particular, each group is directed to different compounds and /or methods. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

INTERNATIONAL SEARCH REPORT

PCT/US02/25691

**Continuation of B. FIELDS SEARCHED Item 3:**

WEST search; CAS search on MEDLINE, CAPLUS, CANCERLIT, EMBASE and BIOSIS  
search terms: interferon hybrid and interferon-tau