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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: USE OF SOMATOSTATIN RECEPTOR AGONISTS IN THE TREATMENT OF HUMAN DISORDERS OF SLEEP HYPOXIA AND OXYGEN DEPRIVATION

(57) Abstract: The invention relates to a method of treating diverse human disorders that may arise, in part, out of sleep hypoxia and oxygen deprivation occurring in the context of sleep apnea/hypopnea disturbances. The disorders that may be treated by the invention comprise gastroesophageal reflux disease (GERD), asthma-associated gastroesophageal reflux (GER), GER-associated asthma, asthma, cardiomyopathy, cardioarrhythmia, congestive heart failure, sudden infant death syndrome, and diverse neurologic conditions. The mode of treatment uses somatostatin receptor ligands (SstRLs), particularly somatostatin-receptor agonists. The invention concerns the method of treatment utilizing, and compositions comprising SstRLs and somatostatin receptor agonists, including agonists of the somatostatin receptor types 2 and 5, particularly, the type 2A receptor (SsR-2A), including octreotide and lanreotide.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/34569

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/00
US CL : 514/16

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. : 514/16

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)
EAST (Internal Patent/Publications DB); NPL-Medline.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 404230223A (FRICKER et al.) 19 August 1992 (19.08.92), abstract (English version attached)(octreotide for the treatment of the gastrointestinal tract (jejunum)).	1-73
X, P	US 2002/0068097 A1 (BASU) 06 June 2002 (06.06.02), paragraph 0013 (octreotide) and paragraph 0076 (GERD treatment).	1-73

Further documents are listed in the continuation of Box C.

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	

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/34569

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.: 1-73 (elected by phone, disease species GERD and somatostatin agonist species octreotide; therein)

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US02/34569.

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) 1-73, drawn to methods of preventing or treating.

Group II, claim(s) 74-80, drawn to methods of preventing or treating

Group III, claim(s) 81-87, drawn to methods of preventing or treating.

Group IV, claim(s) 88-94, drawn to methods of preventing or treating.

Group V, claim(s) 95-101, drawn to methods of preventing or treating.

Group VI, claim(s) 102-108, drawn to methods of preventing or treating.

The inventions listed as Groups I-VI 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:

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

The alleged special technical feature is the use of somatostatin receptor agonists for the treatment of diseases (claim 1-73). However, the drugs are each distinct compounds which different chemical structures, properties and effects. Therefore, since the agonists do not clearly have the same effect on all the different diseases contemplated for treatment, there is no special technical feature among Groups I-VI. Thus, Groups I-VI lack unity.

The first named invention is Group I, claims 1-73, drawn to methods of treating various related diseases using various somatostatin agonists, of which Applicant elected species GERD and octreotide, respectively (if not found, search will be broadened to other species). Pursuant to PCT practice, Applicant was informed that additional fees could be paid for the search of additional inventions (\$210.00 each). Applicant was informed of the right to protest the lack of unity requirement, should additional fees be paid for the search of additional inventions.