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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

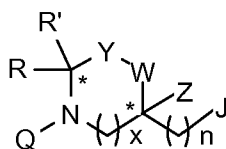
— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

11 December 2008

(54) Title: LINEAR NATRIURETIC PEPTIDE CONSTRUCTS



(I)

(57) Abstract: Linear constructs with an N-terminus and a C-terminus which bind to a natriuretic peptide receptor and include a plurality of amino acid residues and at least one amino acid surrogate of formula I: where R, R', Q, Y, W, Z, J, x and n are as defined in the specification, and optionally at least one prosthetic group covalently bound to a reactive group of at least one of the amino acid residues or surrogates, pharmaceutical compositions including such linear constructs, and methods of treating congestive heart failure or other conditions, syndromes or diseases for which induction of anti- hypertensive, cardiovascular, renal or endocrine effects are desired.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/65656

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 38/10(2006.01)

USPC: 514/14;530/326

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. : 514/14;530/326

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)
Registry, CAPLUS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DUTTA, A. s., Journal of Peptide Science, 2000, Vol 6, pages 321-341, especially pages 326.	1-4, 6, 7, 9, 10
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Y		5, 8, 12-47

☐ 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

"E" earlier application or patent published on or after the international filing date

"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)

"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search

27 August 2008 (27.08.2008)

Date of mailing of the international search report

29 SEP 2008

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/65656

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims 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. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 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 additional fees, this Authority did not invite payment of any additional fees.
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.: 1-53

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US07/65656

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This International Search Authority has found 100 inventions claimed in the International Application covered by the claims indicated below:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are too numerous to recite individually, where exemplary species are those of formulae (IX)-(XII) (claims 51 and 52).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-50 and 53 are generic to a plurality of species, including the specifically recited species of claims 51 and 52, formulae (IX)-(XII).

The first specifically defined species are those of claims 51 and 52 for which claims 1-53 will be searched."

1. This International Searching Authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Annex B, Part I(f) of the Administrative Instructions under PCT states that, "wherein a single claim defines alternatives (chemical or non-chemical)..., the requirement of a technical interrelationship and the same or corresponding Special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature."

The alternatives must comply with subsections (i)(A) and one of either (i)(B)(1) or (i)(B)(2), which requires that, "all alternatives have a common property or activity" and "a common structure is present, i.e., a significant structural element is shared by all of the alternatives" (B)(1) or "in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains." (B)(2).

In the instant case, the compounds are required to have the same activity/function (binding a natriuretic peptide receptor), satisfying requirement (A). However, the claim fails to satisfy either 03)(1) or 03)(2). Claim 1 recites no structure of the peptide, thus failing to meet the requirements of 03)(1), and provides no specific structure for the amino acid surrogate, describing it with a generic structure.

Further, in looking to subsection (f)(iii), it is stated that 'recognized class of chemical compounds' means that, "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved." One of skill in the art would not recognize these divergent compounds, or other compounds asserted to have said activity/function, as required, to function in the context of the instantly claimed invention. Thus, the claim fails to meet the requirement of 03)(2).