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14 April 2011

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Previous Correction:

see Notice of 3 February 2011

(54) Title: PEGYLATED HUMAN APOA-1 AND PROCESS FOR PRODUCTION THEREOF

(57) Abstract: An isolated mono-pegylated apolipoproteinA-1, compositions comprising such, and methods of treating cardiovascular diseases using mono-pegylated apolipoproteinA-1 are provided as well as processes for making isolated mono-pegylated apolipoproteinA-1 and compositions containing such.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/01631

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 38/00, C07K 1/00 (2010.01)

USPC - 514/12, 530/359

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)

USPC -- 514/12, 530/359, 514/171, 530/380

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)
 WEST (PGPB,USPT,USOC,EPAB,JPAB); Dialog Classic Files (654, 652, 349, 6, 35, 65, 155); USPTO Web Page; PCT Patentscope;
 Google Scholar: apolipoprotein A-1, analog, monopegylated, molecular weight, isolated protein
 GenCore 6.3: SEQ ID NO:1

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	WO 2009/036460 A2 (KNUDSEN et al.) 19 March 2009 (19.03.2009) para [0021], [0065]-[0068], [0445], [0640]	1, 4/1, 42 ----- 2-3, 4/2-3
Y	US 2003/0036057 A1 (BRAUN et al.) 20 February 2003 (20.02.2003) para [0016], [0078], SEQ ID NOS: 29-30	2-3, 4/2-3

☐ Further documents are listed in the continuation of Box C.

* 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 but 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

12 November 2010 (12.11.2010)

Date of mailing of the international search report

19 NOV 2010

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/01631

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.: 5-7, 12-29, 35-41, 50-56, 60-72, 78, 79 and 87-89
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:

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.

Group I: claims 1-4, 42, drawn to an isolated mono-pegylated apolipoprotein A-1.

Group II, claims 8-11, 30-34, 43, 57-59, drawn to a composition comprising a carrier and a total molar amount of mono-pegylated apolipoprotein A-1, wherein the total molar amount of mono-pegylated apolipoprotein A-1 is more than 50% relative to the total molar amount of apolipoprotein A-1, wherein the total molar amount of apolipoprotein A-1 includes mono-pegylated apolipoprotein A-1, multipegylated apolipoprotein A-1, and non-pegylated apolipoprotein A-1.

***** 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 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.: 1-4 and 42.

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.

***** Supplemental Box *****

Continuation of: Box III. LOU:

Group III, claim 44, drawn to a high-density lipoprotein particle essentially free of bile salts comprising a pegylated apolipoprotein A-I analog.

Group IV, claims 45-49, 73-77, 80 drawn to a process for preparing an isolated mono-pegylated apolipoprotein-AI.

The inventions listed as Groups I-IV 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:

Groups I, III-IV do not include the inventive concept of a composition comprising a carrier and a total molar amount of mono-pegylated apolipoprotein A-1, wherein the total molar amount of mono-pegylated apolipoproteinA-I is more than 50% relative to the total molar amount of apolipoproteinA-1, wherein the total molar amount of apolipoproteinA-1 includes mono-pegylated apolipoprotein A-1, multipegylated apolipoprotein A-1, and non-pegylated apolipoprotein A-1, as required by Group II.

Groups I-II and IV do not include the inventive concept of a high-density lipoprotein particle essentially free of bile salts comprising a pegylated apolipoproteinA-I analog, as required by Group III.

Groups I-III do not include the inventive concept of a process for preparing an isolated mono-pegylated apolipoprotein-AI, as required by Group IV.

The inventions of Groups I-IV share the technical feature of an isolated mono-pegylated apolipoproteinA-1. However, this shared technical feature does not represent a contribution over prior art. Specifically, WO 2009/036460 A2 to Knudsen et al. (19 March 2009) teaches an isolated (para [0044]) mono-pegylated apolipoprotein A-1 (para [0066]). As said isolated mono-pegylated apolipoproteinA-1 was known at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

The inventions of Groups I-IV therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.