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 US

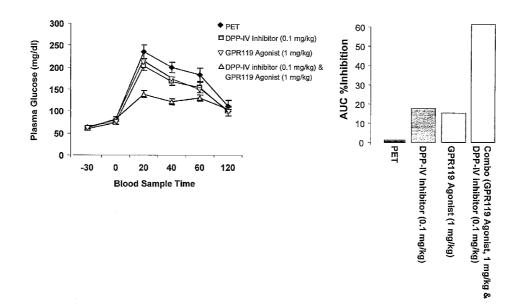
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[Continued on next page]

(54) Title: COMBINATION THERAPY FOR THE TREATMENT OF DIABETES AND CONDITIONS RELATED THERETO AND FOR THE TREATMENT OF CONDITIONS AMELIORATED BY INCREASING A BLOOD GLP-1 LEVEL



(57) Abstract: The present invention concerns combination of an amount of a GPR119 agonist with an amount of a dipeptidyl peptidase IV (DPP-IV) inhibitor such that the combination provides an effect in lowering a blood glucose level or in increasing a blood GLP-1 level in a subject over that provided by the amount of the GPR119 agonist or the amount of the DPP-IV inhibitor alone and the use of such a combination for treating or preventing diabetes and conditions related thereto or conditions ameliorated by increasing a blood GLP-1 level. The present invention also relates to the use of a G protein-coupled receptor to screen for GLP-1 secretagogues.





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European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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A. CLASSIFICATION OF SUBJECT MATTER INV. A61K31/00 A61K31/401

G01N33/58 A61P3/00

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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)

A61K A61P

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, CHEM ABS Data, EMBL

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X Furt	ther documents are listed in the continuation of Box C.	X See patent family annex.					
	ther documents are listed in the continuation of Box C.	X See patent family annex.					
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C(Continua	tion). DOCUMENTS CONSIDERED TO BE RELEVANT				
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Α	WO 03/026661 A (YAMANOUCHI PHARMACEUTICAL CO., LTD; YONETOKU, YASUHIRO; MARUYAMA, TATS) 3 April 2003 (2003-04-03) abstract	1-34			
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Continuation of Box II.1

Although claims 1-11, 18-20, 24-29 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.1

Claims Nos.:

claims 37-39 and 45-47 relate to subject-matters considered by this Authority to be covered by the provision of Rule 67.1(iv) PCT. They are considered to be diagnostic methods practised on the human/animal body as GLP-1 secretagogues are intended to be administered to a mammal and the resulting increase of GLP-1 level in blood is intended to be measured. Hence, it is clear that these latter methods would be performed by skilled medical practitioners. It is also apparent that these methods may be directed to the diagnosis of medical conditions. Thus, it is considered that claims 37-39 and 45-47 include diagnostic methods practised on the human/animal body. Consequently, no preliminary examination will be formulated for the subject-matters of these claims (Article 34(4) (a) (I) PCT).

Continuation of Box II.2

Invention 1: Claims 1-34 have been searched incompletely due to a lack of support and disclosure in the sense of Article 6/5 PCT rending impossible a meaningful search over their whole scope for the following reasons:

- 1. The present claims encompass compositions of compounds defined only by their desired function (namely "GPR119 agonist", "DPP-IV inhibitor") contrary to the requirements of clarity of Art. 6 PCT, because the result-to-be-achieved type of definition does not allow the scope of the claim to be ascertained. In addition, dosage to be administered are defined by a desiderata, "amounts sufficient.." "..to lower a blood glucose level" or "..to increase a blood GLP-1 level" and are therefore not clearly defined (Art.6 PCT). Considering the examples of present application, which involve compositions containing either AR231453 and AR247810 or AR244061 as GPR119 agonist with one DPP-IV inhibitor among MK-0431, LAF237 and FE107542 and their use in the treatment of type II diabetes, the subject-matter of claims 1-34 lacks support and the scope of said claims might be broader than justifyed (Art. 6 PCT).
- 2. Additionally, none of the following denominations "AR231453", "AR247810", "AR244061" and "FE107542" has a generally acknowledged meaning. A skilled person would not be able to determine which

compositions are provided to illustrate and support the subject-matter of present application. He would not even be able to determine which class of GPR 119 agonist and which class of DPP-IV inhibitor are used in compositions providing the reported effect. Because said effect is only reported for four specific compositions (examples 1-3, 14) it is not plausible that all possible combinations intended to be protected involve the same effect. Therefore, the application is considered to lack disclosure (Article 5 PCT). AR231453 and AR244060 being not defined, no meaningful search of the specific examples can be done.

3. A skilled man would not be able to determine which combinations lead to compositions entitled to protection by considering the infinite number of possible compounds intended to be used and defined in pages 109-112, 29-106 and 116-126, table B. Considering the lack of support and disclosure (Article 6/5 PCT), a meaningful search over the whole scope of the claims is impossible. The search of claims 1-34 was restricted to the claimed compositions which appear to be clear and supported, namely to compositions involving a compound already known as GPR 119 or RUP3 inhibitor and a DPP-IV inhibitor being preferably LAF237, MK-0431, BMS-477118, PSN-9301 and SYR-322 as supported by pages 1 and 2 of the description.

In addition, the first composition among the 11718 possibilities implied by the list of table B has been searched, namely a composition comprising [6

-(4-benzenesulfonyl-piperidin-1-yl)-5-nitro-pyrimidin-4-yl]-(4-methanesulfonyl-phenyl)-amine and valine-pyrrolidide and its use in the treatment of type 2 diabetes.

Because of the huge panel of GPR 119 agonists and DPP-IV inhibitors, an objection to lack of unity (Rule 13.1 PCT) could theoretically arise against claims 1-34 because there is no novel or/and inventive feature that could link the single inventions encompassed by said claims so as to form a general inventive concept. However, in this case, given the non limitative nature of both GPR 119 agonists and DPP-IV inhibitors, a meaningful non-unity objection could not be raised.

Invention 2: Claims 35-47 have been searched incompletely due to a lack of support and disclosure in the sense of Article 6 and 5 PCT, thus rending impossible a meaningful search over their whole scope. The use of the expression "treating or preventing a condition ameliorated by increasing a blood GLP-1 level" (claims 35-37, 43-45) does not provide a clear list of diseases for which said screening/diagnostic methods are intended to be used. The augmentation of a biological factor in response to the occupation of a receptor cannot be considered itself as a therapeutic application, even if representing an important piece of scientific knowledge. Such a discovery still needs to find a practical application in the form of a diagnostic method linked to a defined, real pathology or condition. Therefore, the subject-matter of said claims lacks clarity in the sense of Article 6 PCT.

The subject-matter of said claims are considered to lack disclosure in the sense of Article 5 PCT as all the examples of present application solely refer to Type 2 diabetes as disease. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining

the extent of the search of claims 35-47 (PCT Guidelines 9.19 and 9.23). The search has been limited to screening methods to identify agents enabling the secretion of GLP-1 and/or the treatment of conditions such as diabetes and conditions listed in claims 8 and 10 and in page 18, lines 20-24.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

Box 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. X Claims Nos.: — Claims Nos.: — because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 1-11, 18-20, 24-29 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. X 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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 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:
see additional sheet
1. X 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.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-34

a composition comprising a GPR 119 agonist and a DPP IV inhibitor and use thereof in therapy

2. claims: 35-47

A method for identifying GLP-1 secretagogues or compounds useful for treating/preventing a condition ameliorated by increasing a blood GLP-1 level

Information on patent family members

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