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- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

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Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

- (88) **Date of publication of the international search report:**
27 December 2012

(54) **Title:** METHODS AND COMPOSITIONS SUITABLE FOR PREVENTING AND TREATING HYPERLEPTINEMIA

(57) **Abstract:** The invention provides methods and compositions suitable for preventing and treating hyperleptinemia, preventing and treating insulin resistance, preventing and treating cardiovascular disease, preventing and treating obesity, preventing and treating hyperlipidemia, and preventing and treating hypertension in an animal. The methods comprise administering one or more iso-flavones to the animal, preferably in amounts of from about 0.001 to about 10 g/kg/day.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/33873

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 65/00; A61K 36/00 (2012.01)

USPC - 424/757

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)

ICP(8) - A01N 65/00; A61K 36/00 (2012.01)

USPC - 424/757

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 424/725, 514/909

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DiaLog Classic Files -- 2,6,35,64,144,155,315,371,344,347,340,348,349,654,652,345,351; Google Scholar; Search terms -- Hyperleptinemia,leptin, prevent or preventing,treatment, pet, dog, cat, companion, animal,companion animal, isoflavone, isoflavones, nutrition,probiotics,prebiotics, aglycons, glucosides, acetylglucosides, and malonylglucosides,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2007/0110789 A1 (Pan) 17 May 2007 (17.05.2007); para[0014], [0060], [0015], [0053], [0094]-[0095], [0068], [0075], [0074], [0083]; claim 1	1, 3-14, 85,86 ----- 2, 87, 92
X -- Y	WO/2010/019212 A2 (Pan) 18 Feb 2010 (10.02.2010); para[0037], [0039], [0043]-[0046], [0019]; claim 27, 28	88-91,93-98 ----- 2
Y	US 2005/0222050 A1 (Pan) 6 Oct 2005 (06.10.2005); para[0023],[0066]	87
Y	US 2009/0223990 A1 (Bailey et al.) 10 Sep 2009 (10.09.2009); para[0124]	92
A	Lephart et al. 'Dietary isoflavones alter regulatory behaviors, metabolic hormones and neuroendocrine function in Long-Evans male rats', Nutrition & Metabolism, 2004, 1:16, Published: 23 December 2004; Fig 5A; p 5, col 1: section entitled: Circulating Leptin, whole doc.	1-14
A	US 6,592,910 B1 (Banz et al.) 15 July 2003 (15.07.2003) whole doc.	1-14

☐ 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

08 Sep 2102 (08.09.2012)

Date of mailing of the international search report

22 OCT 2012

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/33873

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 extra sheet for continuation -

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.:
1-14, 85-98

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/US 12/33873

Continuation of:

Box NO III. Observations where unity of invention is lacking

Group I: claims 1-14, and 85-98, drawn to a method for preventing and treating hyperleptinemia in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

Group II: claims 15-28, and 85-98, drawn to a method for preventing and treating insulin resistance in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

Group III: claims 29-42, and 85-98, drawn to a method for preventing and treating cardiovascular disease in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

Group IV: claims 43-56, and 85-98, drawn to a method for preventing and treating obesity in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

Group V: claims 57-70, and 85-98, drawn to a method for preventing and treating hyperlipidemia in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

Group VI: claims 71-84, and 85-98, drawn to a method for preventing and treating hypertension in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount.

The inventions listed as Groups I through 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:

The inventions of Groups I-VI comprise distinctive inventive concepts of a method for preventing and treating hyperleptinemia, insulin resistance, cardiovascular disease, obesity, hyperlipidemia, and hypertension, respectively, as outlined above.

The inventions of Groups I-VI share the technical feature of a method for preventing and treating a metabolic disorder in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 6,592,910 B1 to Banz et al. (hereinafter 'Banz'). Banz discloses Claim 15, a method for preventing and treating insulin resistance in an animal comprising administering one or more isoflavones to the animal in a therapeutically effective amount (col 2, ln 65 to col 3, ln 7). As said composition was known in the art at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

Another special technical feature of the inventions listed as Groups I-VI is a pharmaceutical or nutraceutical composition comprising isoflavones and one or more pharmaceutically or nutraceutically acceptable carrier, diluents or excipients. Banz discloses a nutraceutical composition comprising isoflavones and one or more nutraceutically acceptable carrier, diluents or excipients (col 3, ln 14-21, isoflavonoid in combination with dietary ingredients or supplements other than soy proteins). As said composition was known in the art at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I through VI therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.