The examination is being carried out on the **following application documents**

Description, Pages

1-28 as published

Claims, Numbers

1-8 as published

Drawings, Sheets

1/4-4/4 as published

1) Article 53 c) EPC

Claims 1-8 are not acceptable under Art. 53 (c) EPC, since their subject-matter relates to a method of treatment of the human or animal body by surgery or therapy; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods. Accordingly, the said claims were read as if they were worded in a form such as "A composition comprising X for use in preventing or treating disease Y".

2) Article 84 EPC

Claims 1-4 refer to a mechanism of action only, thereby rendering the subject-matter of the claims unclear according to Article 84 EPC, since the wording "activating myocyte AMPK in an animal" or "decreasing the mitochondrial membrane potential" etc. does not characterize real medical indications / diseases.

3) Article 82 EPC

The application lacks unity within the meaning of Article 82 EPC.

The problem(s) to be solved in respect of the present application are "how to provide compositions for activating myocyte AMPK in an animal involving a decrease obesity and obesity complications, increasing insulin sensitivity, decreasing fasting hyper-lipidemia, normalizing hypertension etc.".

The solutions of these problems i.e. provision of herbs or herb-derived compounds as listed in claim 1 are considered to be separate and distinct, because as indicated above the herbs and herbal products are different and do not necessarily have any botanical or other e.g. chemical relationship with each other.

Moreover, since the herbs or herb-derived compounds are different there can be no single general inventive concept in the sense of Article 84 EPC to link each of the claimed methods.

The following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:

Claims 1-8 (partial):

A method for activating myocyte AMPK in an animal in need thereof, said method comprising administering to the subject in need a composition comprising a pharmaceutically effective dose of one or more of the members of the group consisting of phytochemicals or extracts isolated from

invention (1): *Zingiber officinale*

invention (2): *Cotinus coggyria*

invention (3): *Citrus aurantium*

invention (4): Lupulone

invention (5): Whey protein isolate

invention (6): Chromium polynicotinate

invention (7): Hexahydroisoalpha acids, Rho-isoalpha acids, Isoalpha acids, Tetrahydroisoalpha acids

invention (8): Xanthohumol

invention (9): *Sambucu(s ?)*

invention (10): *Gymnema sylvestre*

invention (11): *Camellia sinensis*

invention (12): *Acacia nilotica*

invention (13): *Malus pumila*

invention (14): *Ribes nigrum* L.

invention (15): *Hypericum perforatum*

invention (16): *Theobroma cacao*

invention (17): *Vaccinium, Vaccinium erythroCarpum*

invention (18): *Rosa canina*

invention (19): Leucine

invention (20): *Hydrastis Canadensis*

invention (21): *Vitis vinifera*

invention (22): *Rhamnus purshiana*

invention (23): *Epimedium* (horny goat weed)

invention (24): *Curcuma longa*

invention (25): *Opuntia ficus indica*

invention (26): *Syzygium cumini*

In addition, the prior art document US 2007/015457, cited in the Search Report, already shows botanical compounds such as *acacia nilotica* or xanthohumol, or lupulone or HHIAA or RIAA or THIAA etc. to modulate AMP kinase activity. Therefore, in addition a lack of unity *a posteriori* arises, since the subject-matter of claim 1 is not novel. Hence, there can be no single inventive concept to link each of the aforementioned inventions.

The applicant is asked to state upon which invention or group of inventions further prosecution of the application should be based and to limit the application accordingly. The other invention or group of inventions is to be excised from the claims, description and drawings if any.

The subject-matter to be excised may be made the subject of one or more divisional applications according to Rule 36 EPC.

4) Prior art

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 DATABASE FSTA [Online]
INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANkFURT-MAIN, DE;
AL-AMIN Z M ET AL: "Anti-diabetic and hypolipidaemic properties of ginger (Zingiber officinale) in streptozotocin-induced diabetic rats.",
XP002678104,
Database accession no. FS-2007-07-Te1076 ; & BRITISH JOURNAL OF

NUTRITION,
vol. 96, no. 4 , pages 660-666,
BRITISH JOURNAL OF NUTRITION 2006 CORRESPONDENCE ADDRESS, M. ALI, DEP. OF BIOL. SCI., FAC. OF SCI., KUWAIT UNIV., PO BOX 5969, 13060-SAFAT, KUWAIT. FAX +965 4847054. E-MAIL ALIMUSLIM@HOTMAIL.COM

D2 B.H. ALI ET AL.: "Some phytochemical, pharmacological and toxicological properties of ginger (Zingiber officinale Roscoe): A review of recent research",
FOOD AND CHEMICAL TOXICOLOGY,
vol. 46, no. 2, February 2008 (2008-02), pages 409-420, XP0022399084, ISSN: 0278-6915, DOI: DOI:10.1016/J.FCT.2007.09.085

D3 KADNUR VENKATACHALAPATHI SANJAY ET AL: "BENIFICIAL EFFECTS OF ZINGIBER OFFICINALE ON EXPERIMENTALLY INDUCED OBESITY",
FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY.ANNUAL MEETING. ABSTRACTS OF PAPERS, XX, XX,
no. 4/05, 1 January 2004 (2004-01-01), XP009060482,

D4 WO 03/075941 A1 (NUTRICIA NV [NL]; RAGGERS RENE JOHN [NL]; VERLAAN GEORGE [NL]) 18 September 2003 (2003-09-18)

D5 US 2007/154576 A1 (TRIPP MATTHEW L [US] ET AL) 5 July 2007 (2007-07-05)

The following comments refer to invention (1) / *Zingiber officinale* only.

The subject-matter of claims 1, 3-8 is not considered as being novel for the reasons as follows.

D 1 already reports on antidiabetic and hypolipidaemic properties of ginger (*Zingiber officinale*) in streptozotocin-induced diabetic rats.

D 2 is a review of recent research about properties of ginger (*Zingiber officinale*):

Ginger extract improved insulin sensitivity, has hypoglycemic, hypocholesterolemic and hypolipidemic potential, is useful for managing the effects of diabetic complications and lowers blood pressure etc.

D 3 relates to *Zingiber officinale* methanolic extract which showed significant reduction in fasting glucose, cholesterol, triglyceride and body weight levels as compared to obese control group.

D 4 already refers to a method for the prevention and/or treatment of overweight and/ or stimulating energy expenditure in mammals, comprising the enteral administration to a mammal of a preparation comprising an effective amount of a combination of dill and one or more components capable of stimulating in vivo lipolysis including *Zingiber officinale* or an isolate thereof etc..

D 5 already reports on botanical compounds such as *acacia nilotica* or xanthohumol, or lupulone or HHIAA or RIAA or THIAA etc. to modulate AMPK kinase activity.

5) A third party observation under Article 115 EPC has been filed, wherein Exhibits **1-14** from India's Traditional Knowledge Digital Library (TKDL) were submitted.

Briefly summarized, the Exhibits have the following contents:

Exhibit **1** and Exhibit **8** relate to the efficacy of *Vitis vinifera* orally for the treatment of Diabetes mellitus and obesity, respectively.

Exhibit **13** refers to the oral efficacy of *Vitis vinifera* for the treatment of hypertension.

Exhibit **2** refers to the oral usefulness of *Curcuma longa* for the treatment of Diabetes mellitus.

Exhibit **3**, Exhibit **4** and Exhibit **5** refer to the oral usefulness of *Gymnema sylvestre* for the treatment of Diabetes mellitus.

Exhibit **6** refers to the oral usefulness of *Curcuma longa* and of *Acacia nilotica* for the treatment of Diabetes mellitus.

Exhibit **7** refers to the oral usefulness of *Zingiber officinale* and of *Citrus aurantium* for the treatment of e.g. Diabetes mellitus.

Exhibit **9** refers to the oral usefulness of *Zingiber officinale* for the treatment of Obesity.

Exhibit **10** shows the oral efficacy of *Curcuma longa* for the treatment of Obesity.

Exhibit **11** refers to the oral efficacy of *Syzygium cuminii* for the therapy of Obesity.

Exhibit **12** relates to the oral usefulness of Ginger (*Zingiber officinale*) for the treatment of hypertension.

Exhibit **14** shows the efficacy of *Zingiber officinale* and of *Vitis vinifera* for the oral treatment of hypertension / hypotension, angina pectoris etc..

Exhibits **7, 9, 12** and **14** are relevant with regard to invention 1 as mentioned above, since they relate to *Zingiber officinale* and its usefulness for the treatment of Diabetes mellitus, Obesity, hypertension etc..

As diabetes and hypertension are considered as obesity complications, the subject-matter of at least the claims 1, 4-8 is not regarded as being novel in view of the disclosure of Exhibits **7, 9, 12, 14**.

6) The above mentioned objections should be overcome by suitable amendment or explanation. If not, refusal of the application (Art. 97 (2) EPC) should be expected.

In the case where new claims are filed, they should be accompanied by carefully adapted pages of the description (Rule 42 (1) EPC).