Datum

Date Date cf Form 1507

Sheet Feuille Anmelde-Nr:

Application No: 08 765 961.

Demande nº:

The examination is being carried out on the following application documents

#### Description, Pages

1-33

as published

### Claims, Numbers

1-26

as published

#### Drawings, Sheets

1/11-11/11

as published

### 1. Cited documents:

1.1 The following documents were cited in the ISR and SESR (the references are made to the passages cited in the search report):

### ISR:

D1: SHAO Z.-H. ET AL.: "Antioxidant effects of American ginseng berry extract in cardiomyocytes exposed to acute oxidant stress", BIOCHIMICA ET BIOPHYSICA ACTA, vol. 1670, 2004, pages 165-171, XP004491176,

D2: US 2003/152544 A1

D3: RHY J.-K. ET AL.: "Free radical-scavenging activity of Korean red ginseng for erectile dysfunction in non-insulin-dependent diabetes mellitus rats", UROLOGY, vol. 65, no. 3, 2005, pages 611-615, XP004789802.

D4: KANG S.Y. ET AL.: "Ginsenosides of the protopanaxatriol group cause endothelium-dependent relaxation in the rat aorta", LIFE SCIENCE, vol. 56, no. 19, 1995, pages 1577-1586, XP001162793,

D5: CHEN X. ET AL.: "Ginsenosides-induced nitric oxide-mediated relaxation of the rabbit corpus cavernosum", BRITISH JOURNAL OF PHARMACOLOGY, vol. 115, 1995, pages 15-18, XP002110278,

### SESR:

D6: A. S. ATTELE ET AL: "Antidiabetic Effects of Panax ginseng Berry Extract and the Identification of an Effective Component", DIABETES, vol. 51, no. 6, 1 June 2002 (2002-06-01), pages 1851-1858, XP055054573, ISSN: 0012-1797, DOI: 10.2337/diabetes.51.6.1851

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D7: MEHENDALE S R ET AL: "Chronic pretreatment with American ginseng berry and its polyphenolic constituents attenuate oxidant stress in cardiomyocytes", EUROPEAN JOURNAL OF PHARMACOLOGY, ELSEVIER SCIENCE, NL, vol. 553, no. 1-3, 28 December 2006 (2006-12-28), pages 209-214, XP028029383, ISSN: 0014-2999, DOI: 10.1016/J.EJPHAR.2006.09.051 [retrieved on 2006-12-28]

D8: JP 2000 212080 A

# 2. Article 123(2) EPC:

2.1 No amendments have been made.

## 3. Observation of third party:

3.1 With a letter of 13.7.2010 an observation of third party has been filed. The document annexed to this observation (Exhibit 1, pg 03-05, referring to a formulation containing Panax ginseng Wall. Syn.: P. s. Nees as a single ingredient used as a semen promoter) has been taken into account by the Searching Authority. However, this document has not been found to be relevant for novelty as it does not refer to a specific part of ginseng namely, a berry. The Applicant should be aware of the fact that this document would be used for attacking inventive step.

### 4. Novelty:

- 4.1 Novelty of subject-matter of claims 1-20,22 and 24-26 appears to be anticipated by the prior art; see reasoning as follows:
- 4.2 First, the term "for facilitation of blood circulation" or "prevention of vascular aging" or "for treatment of vascular inflammation" or "for facilitation of angiogenesis" or "for treatment of ischemic heart disease" or "for treatment of local blood circulation insufficiency" or "for improvement of skin beauty" or "for improvement of male sexual function" can be regarded only as an intended purpose of a compound which does not provide any limitation of scope of the claim. Thus, any prior art disclosing the claimed composition being merely suitable for such a purpose is a novelty destroying.
- 4.3 Thus, any of D1,D2,D6 and D7 (see the passages cited in the SR), anticipates novelty of claims 1,3,5,7,9,10,12,14-18, 20,24-26.
- 4.4 Furthermore, the subject-matter of claims 2,4,6,8,11,13 is anticipated by D1 (see the passages cited in the SR) and the subject-matter of claims 19 and 22 by D1,D2 and D7.

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4.5 The subject-matter of claims 21 and 23 was not disclosed in any available prior art and seems to be novel.

# 4.6 In case of reformulating the claims:

- 1) Even if the present claims are reformulated into a medical use format of claims by introducing the term "for use in....(i.e. the above stated intended uses)", such a format would not be generally regarded as to be appropriately written for the following reasons (i.e. objections under Article 84 EPC would be raised):
- a) the definition of a therapeutic method only in terms of a mode of action, namely "for facilitation of blood circulation" or "prevention of vascular aging" or "for facilitation of angiogenesis", is generally not accepted, as it relates to a proposed theory underlying the activity of the therapeutic agent (no clear medical indication is given),
- b) no restriction to ill subjects is made at all as such a situation naturally occurs in healthy persons,
- c) by using the above wording, a in vitro method is covered as well,
- d) improvement of skin beauty can be regarded only as referring to a cosmetic purpose which cannot make a benefit from a medical use format of claim.

Thus, such claims would be still regarded as referring to a product as such.

- 2) Moreover, in view of the above amendments, the application would be regarded as to be non-unitary:
- a) the application would be regarded as to relate to 7 inventions; the reasons would be as follow:

The problem to be solved by the present invention is:

- i) facilitation of blood circulation or treatment of local blood circulation insufficiency,
- ii) prevention of vascular aging,
- iii) treatment of vascular inflammation,
- iv) facilitation of angiogenesis,
- v) treatment of ischemic heart disease,
- vi) improvement of skin beauty,
- vii) improvement of male sexual function.

The proposed solution to the posed problems is the use of:

a) a composition comprising a ginseng berry extract.

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Even if the present application would therefore provide a related solution for different underlying technical problems, namely by using said composition in medicine, such a solution as known in the art would not serve as unifying feature of these groups of inventions:

see any of D1,D2;D6 or D7 disclosing an extract of ginseng berry having antioxidative properties and therefore preventing CVD (D1 or D7), for use as a skin care product (D2), for use in the treatment of DM, obesity and preventing arteriosclerosis (D6).

## 5. Inventive step:

5.1 The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 21 and 23 does not involve an inventive step within the meaning of Article 56 EPC; the reasons being as follow:

D1 disclosing the use of a composition comprising a ginseng berry extract "being suitable for improving male sexual function" (see objections stated above under point 4.2) can be regarded to be the closest prior art.

The present application differs from D1 in that:

- the claimed composition further comprises l-arginine (claim 21) at concentration 0.01%-99.9% weight% of the extract (claim 23).

The problem to be solved may be therefore regarded as how to provide an alternative to the known composition.

In general, ginseng extracts have already been employed in the art for treating erectile dysfunction (see any of D3 or D5 or Exhibit 1 filed with the third party observation; i.e the same properties would be expected in case of an extract prepared from the specific part of ginseng, namely berry). Moreover, the mechanism underlying said effect, namely the production of NO has been demonstrated (see D4 or D5). Also the L-arginine as such has been used for such a purpose (see D8 disclosing the use of L-arginine at the claimed concentration for treating erectile dysfunction). Thus, skilled person being aware of the above teaching would regard as an obvious option to add L-arginine into the ginseng berry extract of D1, without exercising inventive skill, in order to solve the problem posed. Thus, no inventive step of claims 21 and 23 can be acknowledged.