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Anmelde-Nr:  
Application No: 06 810 359.7  
Demande n°:

EP 1927361  
13-11-12

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

#### Description, Pages

1-10, 12-24, 26-40 as annexed to the Int. Prel. Examination Report  
11, 25 filed with entry into the regional phase before the EPO

#### Claims, Numbers

1-7 filed with entry into the regional phase before the EPO

#### 1. References:

- D1 WO 2004/105770 A1  
D2 JP 2000 319190 A  
D3 JP 2003 286185 A  
D4 JP 10 036283 A  
D5 PANOSYAN A.G. ET AL.: "Sterols and sterol glycosides of Bryonia alba", KHIMIYA PRIRODNYKH SOEDINENII, no. 3, 1977, pages 353-360, XP003010652  
D6 WO 2005/095436 A1/ Patent family member EP1731527  
D7 WO 2006/123464 A1/ Patent family member EP1882477  
D8 WO 2006/123465 A1/ Patent family member EP1808175  
D9 "Health care food for maintaining intestinal health and assisting to reduce abdomen fat", WPI / THOMSON, vol. 2003, no. 63, 2 July 2003 (2003-07-02), XP002597480.  
D10 CHOI J C ET AL: "Effect of Allium victorialis var.platyphyllum leaves on triton WR-1339-induced and poloxamer-407-induced hyperlipidemic rats and on diet-induced obesity rats" MEDICINAL & AROMATIC PLANTS ABSTRACTS, SCIENTIFIC PUBLISHERS, SCIENTIFIC PUBLISHERS, NEW DELHI - INDIA, vol. 27, no. 6, 1 December 2005 (2005-12-01), XP018011794, ISSN: 0250-4367

D11 EP 1 927 360 A1 (MORINAGA MILK INDUSTRY CO LTD [JP]) 4 June 2008  
(2008-06-04)

D12 EP 1 930 013 A1 (MORINAGA MILK INDUSTRY CO LTD [JP]) 11 June 2008  
(2008-06-11)

-**D1** discloses a composition for incorporation into foods and nutraceuticals which comprises phytosterols and/or phytostanols and glucomannan. Aloe may be used as source of glucomannan.

-**D2** discloses an obesity preventing and improving agent which comprises aloe extract as active ingredient. See abstract.

-**D3** discloses an Aloe vera pressed liquid for treating non-insulin dependent-diabetes mellitus. See abstract

-**D4** discloses a fibroblast growth promoter which contains an aqueous extract of *Chlorella*, *Oocystaceae*, and an extract of *Aloe barbadensis* or *Aloe Vera*. The agent can be used as it is or e.g. in the form of a food or drink. See abstract

-**D5** discloses the composition and content of phytosterols and their glycosides (such as e.g. 3-O-beta-D-glucopyranosyl-4-methylstigmast-7-en-3-ol) in *Bryonia alba* roots (*Cucurbitaceae*). See p. 354, cpd I.

-**D6** discloses the compound 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol (compound I of the present invention), a drug and food or drink containing the same and its use for preventing and treating hyperglycemia and complications e.g. diabetic retinopathy. The composition may be an extract of a plant of the family *Liliaceae*.

See attached patent family member EP1731527: claims, par. 50.

-**D7** refers to the compound 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol (compound I of the present invention), a glycoside extracted and purified from *Aloe vera*, which may be used in the form of a drug, food or drink for improving pancreatic function for preventing and treating diseases such as neuropathy, nephropathy, retinopathy, cataract and diabetes.

See attached patent family member EP1882477: claims.

-**D8** refers to compounds such as 4-methylcholest-7-en-3-ol, 4-methylergost-7-en-3-ol and 4-methylstigmast-7-en-3-ol (no glycosides) and corresponding extracts from *Aloe vera*. They may be used in the form of drug, food or drink for improving pancreatic function and for preventing and treating diseases such as neuropathy, nephropathy, retinopathy, cataract and diabetes.

See attached patent family member EP1808175: claims.

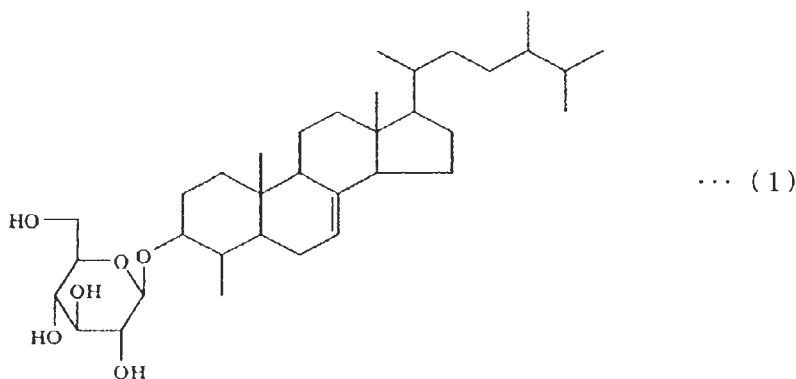
-**D9** discloses a health-care food for reducing abdomen fat which contains amongst others aloe.

-In **D10**, Allium extracts reduced retroperitoneal, epidymal- and total abdominal fat in obese rats.

-**D11** discloses a visceral fat accumulation inhibitor for preventing and treating obesity, which contains a compound having lophenol structure such as 24-methyllophenol (no glycoside). The active ingredient may be in the form of an organic solvent extract or a hot water extract of a Liliaceae plant, such as Aloe vera.

-**D12** discloses an insulin resistance improving agent for preventing morbid condition relating to insulin resistance which comprises 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol or organic/hot water extract of plant of Liliaceae family. The active agent has an effect on decreasing risks, prevention, improvement or treatment of the diseases involved in the insulin resistance such as obesity. See par. 30, claims.

2. The subject-matter of present claim 1 is an agent for inhibiting visceral fat accumulation, comprising a compound represented by the following chemical formula (I) as an active ingredient.



3. D6 was published on 13.10.05 and filed on 30.03.05. It has been supplied to the European Patent Office in one of its official languages and the national fee provided for in Art. 22(1) or Art. 39(1) PCT has been paid. The requirements of Art. 158(2) EPC 1973 are thus fulfilled. Its content as filed is therefore considered to be comprised in the state of the art relevant to the question of novelty, pursuant to Art. 54(3) and (4) EPC 1973.

D6 discloses the compound 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol (compound (I) of the present invention), a drug and food or drink containing the same and its use for preventing and treating hyperglycemia. The compound or the composition is contained in food or drink in an amount of 0.0001 to 1% by mass. The composition may be an extract of a plant of the family Liliaceae. See attached patent family member EP1731527: claims, par. 50.

Thus, it is prejudicial to the novelty of the subject-matter of claim 1 of the present application in so far as the same contracting states are designated.

The same applies mutatis mutandis to the subject-matter of claims 2-5.

It is explicitly pointed out that the intended use *for inhibiting visceral fat accumulation* does not render the agent new.

The attention of the applicant is drawn to the fact that according to Art. 54(5) EPC, substances or compositions for which a first medical use is already known may subsequently be patented for **a further, specific use** of that kind, in which case the indication of this further therapeutic application can establish novelty in the claim. A claim for a further medical use should be drafted as "Substance/composition for use in the treatment of .....". In addition, the therapeutic application should allow a practical application in the form of a defined, real treatment of a pathological condition (disease). See Guid. G.VI.7.1.

4. D7 was published on 23.11.06 and claims the priority date of 17.05.05. It has been supplied to the European Patent Office in one of its official languages and the national fee provided for in Art. 22(1) or Art. 39(1) PCT has been paid. The requirements of Art. 158(2) EPC 1973 are thus fulfilled. Its content as filed is therefore considered to be comprised in the state of the art relevant to the question of novelty, pursuant to Art. 54 (3) and (4) EPC 1973.

D7 refers to the compound 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol (compound I of the present invention), a glycoside extracted and purified from Aloe vera, which may be used in the form of a drug, food or drink for improving pancreatic function for preventing and treating diseases such as neuropathy, nephropathy, retinopathy, cataract and diabetes. The compound or the composition is contained in food or drink in an amount of 0.0001 to 1% by mass (cl. 8). The composition may be an extract of a plant of the family Liliaceae. See attached patent family member EP1882477: claims.

Thus, it is prejudicial to the novelty of the subject-matter of claim 1 of the present application in so far as the same contracting states are designated.

The same applies *mutatis mutandis* to the subject-matter of claims 2-5.

It is explicitly pointed out that the intended use *for inhibiting visceral fat accumulation* does not render the agent new. See item 3.

5. The applicant is invited to file a translation of the previous application JP 2005275171, whose priority is claimed, into one of the official languages of the European Patent Office (Rule 53(3) EPC), as the validity of the priority claim shall be checked for determining patentability of the subject-matter claimed.

6. D12 was published on 11.06.08 and claims the priority date of 30.09.05.

D12 discloses an insulin resistance improving agent for preventing morbid condition relating to insulin resistance which comprises 3-O-beta-D-glucopyranosyl-4-methylergost-7-en-3-ol or organic (compound I of the present invention). The active agent has an effect on decreasing risks, prevention, improvement or treatment of the diseases involved in the insulin resistance such as **obesity**. D12 discloses a food or drink containing the agent in an amount of 0.0001%. The composition may be an extract of a plant of the family Liliaceae. See par. 30, claims.

D12 will be considered prejudicial to the novelty of the subject-matter of claim 1 of the present application if the priority of the present application (JP2005275171 and JP2005287887) is found not to be valid and if the priority of D12 is found to be valid, in so far as the same contracting states are designated (Art. 54(3) and (4) EPC 1973).

The same applies *mutatis mutandis* to the subject-matter of claims 2-7.

7. Furthermore, the present application does not meet the requirements of Art. 52(1) EPC because the subject-matter of claims 2-3 is not new within the meaning of Art. 54 (1) and (2) EPC.

D2 discloses an obesity preventing and improving agent which comprises Aloe extract as active ingredient. See abstract.

D9 discloses a health-care food for reducing abdomen fat which contains amongst others Aloe. See abstract.

In D10, *Allium* (Liliaceae) extracts reduced retroperitoneal, epidymal- and total abdominal fat in obese rats.

D2 and D9-10 do not refer to compound (I). However, seen that the extraction procedure described in the present application is a common one, it is considered to be implicit that the compositions disclosed in the prior art, which are known to have the same antiobesity/ abdominal fat reducing effect as described in the present application, comprise the compound of formula I.

Therefore documents D2 and D9-10 are novelty-destroying for the subject-matter of claims 2-3.

If priority of the present application is found not to be valid, D11 may also be considered prejudicial to the novelty of claims 2-3 (Art. 54(3) EPC)- provided the priority of D11 is found to be valid, as D11 discloses a visceral fat accumulation inhibitor for preventing and treating obesity, which contains an organic solvent extract or a hot water extract of a Liliaceae plant, such as Aloe vera.

*Remark*

The treatment of obesity overlaps with the reduction of visceral fat.

The applicant's attention is drawn to the fact that the mere explanation of an effect obtained when using a compound in a known process, even if the explanation relates to a pharmaceutical effect which was not known for that compound, cannot confer novelty to said process. In the present case, the newly discovered technical effect of reducing visceral fat accumulation does not confer novelty on the claims directed to the use of a known aloe extract for a known purpose (treatment of obesity). No novelty exists, if the claim is directed to the use of a known compound for a known purpose, even if a newly discovered technical effect (the reduction of visceral fat) underlying said known use is indicated in that claim.

The subject-matter of claims 6-7 would therefore also lack novelty over D2, D9-12 which disclose compound (I) or a Liliacea extract for treating/preventing obesity or inhibiting visceral (abdominal) fat accumulation (Art. 54(2)-(3) EPC).

8. Exhibits 1-7 from the Traditional Knowledge Digital Library/ TKDL have been provided by Third Party under Art. 115 EPC. These citations refer to oral formulations comprising Aloe vera extracts for the treatment of obesity. They are considered novelty-destroying for the subject-matter of claims 2-3, 6-7 for the same reasons as outlined under item 7. (Art. 54(1) and (2) EPC).

9. Claims 6-7 do not meet the requirements of Art. 84 EPC as the therapeutic application of the products is defined by the underlying mechanism of action (inhibition of visceral fat accumulation), which does not allow any practical application in the form of a defined, real treatment of a pathological condition (disease) (Guid. G.VI.7.1).

10. The applicant is invited to file new claims which take account of the deficiencies mentioned in the opinion.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 123(2) EPC).