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

Main Request

Description, Pages

1-16 as published

Claims, Numbers

1-9 received on 11-02-2014 with letter of 11-02-2014

Drawings, Sheets

1/5-5/5 as published

Auxiliary Request 1

Description, Pages

1-16 as published

Claims, Numbers

1-9 received on 11-02-2014 with letter of 11-02-2014

Drawings, Sheets

1/5-5/5 as published

Main Request

1 **Art. 123(2) EPC**

Amended claim 1 is based on former claim 9 and has been specified to a composition for use in reducing a subject's desire to eat, comprising an effective amount of an extract from *Mucuna pruriens*, which contains L-DOPA,

and an extract from *Nelumbo nucifera*, which contains aporphine alkaloid and pharmaceutically acceptable excipients. wherein the amountof **L-DOPA** is **50 mg to 500 mg** and the amount of **aporphine alkaloid** is **2 mg to 50 mg per dose.** Support for claim 1 can be derived from paras.[0031] to [0033] of the application as filed (WO 2010/121159). Present claim 2 relies on former claim 10 and amended claims 3-9 are based on previous claims 11-17. As no subject-matter has been added, the requirements of Art. 123(2) EPC are deemed to be fulfilled.

2 **Clarity and Sufficiency (Arts. 84 and 83 EPC)**

The claims as amended overcome the objections previously raised against the generic terms *"dopamine precursor"*, *"dopamine agonist"* and *"physiological condition"*.

The non-limiting term *"..composition for use in reducing a subject's desire to eat..."* apparently covers **both a therapeutical and/or non-therapeutical** use.

3 **Art. 53(c)**

In view of the amended claims as presently on file, the previously raised objection (against former claim 7) has been rendered moot.

4 **Novelty (Arts. 52(1) and 54(1) EPC**

Claim 1 as amended now refers to a composition for use in reducing a subject's desire to eat, comprising a defined amount of an extract from *Mucuna pruriens* containing L-DOPA and an extract from *Nelumbo nucifera*, containing aporphine alkaloid as specified therein.

D4, WO 98/02165, discloses compositions for reducing **appetite and carbohydrate craving** using precursors of serotonin, dopamine, norepinephrine, tryptophan, phenylalanine, tyrosine and histidine (cf. abstract, page 5, lines 16-33). D4, however, does not disclose a composition comprising the extract of *Mucuna pruriens* **and** *Nelumbo nucifera*, containing L-DOPA and aporphine alkaloid in the defined amounts.

As regards the documents D1-D3, the Examining Division concurs with the Applicant in that none of these documents discloses the treatment of disorders of eating behaviors, but **maintains that these documents disclose the use of a composition comprising a dopamine precursor and/or a dopamine agonist in the treatment of a "psychological condition"**.

D1 discloses aporphine esters and their use in the treatment of Parkinson's disease, hemicrania, restless legs syndrome (RLS) and psychotic disorders (cf. abstract, para. 1 at page 1, lines 9-32 at page 6, page 23, lines 6-34, furthermore claims 1/12/14 and 15).

D2 relates to the use of a solid pharmaceutical composition containing carbidopa and levodopa in the treatment of Parkinson's disease and other movement related disorder, diseases and syndroms (cf. abstract, page 30, lines 1-14).

D3, US 2006/165822 A1 (VAN DER GIESSEN ET AL.) 27 July 2006 (2006-07-27), cited in the WOISA, provides pharmaceutical compositions comprising Mucuna pruriens seeds or its components/fractions or mixtures for preventing/treating or alleviating neurological diseases. In addition, D3 relates to the use of Mucuna pruriens seeds for the treatment of Parkinson's disease to obtain a broader therapeutic window in L-Dopa therapy (cf. abstract, page 2, section [0012], page 7, section [055], section [0081] at page 9).

As none of the cited documents discloses the features according to the amended claim 1, novelty over the prior art has to be acknowledged.

5 Inventive step (Art. 56 EPC)

The problem to be solved resides in the provision of a composition conferring a reduced interest in food and additionally exhibiting an improved safety. Accordingly, the examples 4-7 at pages 13-16 provide evidence that patients who have been administered the claimed composition pursuant to the formulations in examples 1-3 of the application, reported a reduced interest in food intake (lack of appetite and interest in eating).

5.1 Third Party observations (Art. 115 EPC)

Concerning the third parties comments, it has to be noted, in accordance with the Applicant, that the cited exhibits 1-6 do not disclose the administration of a composition as specified in the present claims as amended.

Exhibit 3 discloses formulations comprising **Nelumbo nucifera** having satiating properties. **Exhibits 5/6** relate to therapeutic compositions comprising **Nelumbo nucifera** for the treatment of excessive hunger.

Although silent on a composition comprising a defined amount of an extract from *Mucuna pruriens* containing L-DOPA and an extract from *Nelumbo nucifera*, containing aporphine alkaloid as specified therein, the skilled man is well aware of the **beneficial effects of Nelumbo in the treatment of excessive hunger** which is to be considered as an eating disorder. So far, and **in the absence of comparative data with regard to formulations of Nelumbo nucifera having satiating properties** and as further alternative composition for use in reducing a subject's desire to eat, the claimed subject-matter does not appear to distinguish in a non-obvious and inventive way over the prior art knowledge. Therefore, the requirements of inventive step are not deemed to be fulfilled with regard to the third partie's intervention.

Auxiliary Request

1 **Arts. 84 and 123(2) EPC**

The term *"non-therapeutic use"* in amended claim 1 **cannot** be explicitly derived from the application documents as filed (in particular from original claim 14 as indicated by the Applicant in his letter of 11/02/2014).

2 **Novelty and Inventive step**

Concerning the issues of novelty and inventive step the same arguments and objections apply as for the Main Request above.

In the absence of comparative data with regard to formulations of **Nelumbo nucifera having** satiating properties and the present composition representing a *further alternative* composition, the skilled man is well aware of the beneficial effects of Nelumbo in the treatment of excessive hunger which is to be considered as an eating disorder. Moreover, it has to be noted that a formulation including Nelumbo is probably and very likely administered within the time period of between 30 and 90 minutes before starting to eat and wherein the amount of L-DOPA is 50 mg to 500 mg and the amount of aporphine alkaloid is 2 mg to 50 mg per dose, features which are quite broad and not as specific as to distinguish in a non-obvious and inventive way.

Objections applying both Main and Auxiliary Requests

1 Passages throughout the description referring to a method of treatment are to be removed or so redrafted as to indicate a possible application of the invention.

2 Incorporations made by reference throughout the description (section [0001]) are not accepted in the working practice of the EPO.

3 General statements in the description trying to extend the scope of protection in an ambiguous way (cf. page 10, last para.) are to be removed (cf. in the Guidelines of the EPC, F-IV, 4.4, previous C-III, 4.4).