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

**Description, Pages**

1-16 as published

**Claims, Numbers**

1-17 received on 14-05-2013 with letter of 13-05-2013

**Drawings, Sheets**

1/5-5/5 as published

1 The present application concerns a method of modulating the dopaminergic system of the CNS comprising the administration of a *"dopamine precursor"* and/or a *"dopamine agonist"* in an amount effective to induce a "reward response" in a subject, said reward response simulating a desired state of being in said subject. Hereby, said desired state of being to be achieved consists of a reduced interest in food, a reduced craving for food or a feeling of having already eaten and wherein said desired state is achieved within 90 minutes.

2 Whereas the induction of a reward response simulating a feeling of "having already eaten" can be clearly derived from para. [0007] of the application, the basis for the *"treatment of disorders of eating behavior"* as set forth in present claims 1 and 9 **cannot be clearly and unambiguously** derived from the application (cf. paras. [0006] and [0021]) as indicated by the Applicant in his reply of 14/05/2013. Therefore, the requirements of Arts. 84 and 123(2) EPC are not deemed to be entirely fulfilled.

3 Novelty and inventive step (Arts. 52(1), 54(1) and 56 EPC

Dopamine precursors and dopamine agonists in the treatment of "disorders of eating behaviors" by inducing/simulating a feeling of satiety or of having already eaten are apparently known from the prior art:

WO 98/02165, (D4) as exemplary document, 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). At page 14, lines 19-31, the (oral) administration of phenylalanine or tyrosine formulation at 10.00 a.m. and at

3.00 p.m. is depicted, thus including a dosage schedule of 90 minutes before lunch. The dosage schedule in example 1 of page 15 includes the tyrosine dose at 10.00 a.m. and at 3.00 p.m., hereby implicitly including the administration within 90 minutes before the next meal. As such, the teaching of D4 falls into the scope of the present application.

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).

4 Third Party observations (Art. 115 EPC)

The Applicant's comments with regard to cited exhibits 1-6 have been considered. Said documents do not disclose the administration of dopamine precursors/agonists within 90 minutes before the subject eats a meal.

However, it has to be also considered that **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 dopamine precursors/agonists and to their administration "within" 90 minutes before intake of a meal, 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, such formulation

including Nelumbo is probably and very likely administered within the time period of 90 minutes before starting to eat. So far, and **in the absence of convincing experimental data with defined dopamine agonists/ precursors**, the administration within the indicated time period of 90 minutes cannot be considered as a technical feature distinguishing the presently claimed subject-matter 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.

5 Art. 53(c) EPC

The Examining Division maintains its view that the term *"treating a physiological condition"* in the present claim 7 encompasses the treatment of the human or animal body by therapy and is, therefore, non-patentable in view of Arts. 53(c) EPC. The same applies to the corresponding passages throughout the description, referring to a method of treatment of the animal/ human body.

6 Arts. 83 and 84 EPC

The generic terms *"dopamine precursor"* and *"dopamine agonist"* in the claims do not provide any information as to the structural or technical features of the intended compounds. Said unclear definitions hence put an undue burden on the skilled person seeking to establish the scope of the claims and willing to carry out the invention over the whole of the broad field claimed.

A similar objection has to be raised with regard to the general term "physiological condition" in claim 7, encompassing a numberless amount of possibilities and as such leave the skilled man at a loss when trying to determine the exact scope of protection.

7 As matters stand, the present application is still deficient in such a way to be far from patentability in accordance with the regulations of the EPC. In the event that the raised objections are not addressed in a convincing way, invitation to oral proceedings to reach a final decision may become necessary with the next examination report.

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

9 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).