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Sheet 1
Feuille

Anmelde-Nr.
Application No: 10 756 446.0
Demande n°:

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

Description, Pages

1-52 as published

Claims, Numbers

1-15 received on 14-05-2012 with letter of 14-05-2012

Drawings, Sheets

1/11-11/11 as published

- 1 The present claims finds basis in the application documents as initially filed (cf. Applicant's letter of 14/05/2012). As no subject-matter has been added, the requirements of Art. 123(2) EPC are deemed to be fulfilled.
- 2 The present application relates to methods/compositions providing new therapeutic strategies focusing on neural repair and restoring neurological functions including the promotion of neuronal outgrowth and proliferation. In view that clinical repair of central nervous system (CNS) lesions and recovering neurological functions is difficult, the problem to be solved resides in the provision of improved regenerative therapies which can promote neuronal outgrowth and proliferation of neurons in order to re-establish damaged or diseased nerves to function again.

Claims 1-6 concern a composition comprising at least **two** herbal components selected from the group as depicted therein for use in a method of promoting neuronal outgrowth and proliferation of neurons in tissues of the central/peripheral nerve system.

Claim 7 relates to a composition comprising at least **three** of the herbal components as defined therein for use in the treatment of patients having a condition selected from the group of depression/psychiatric indications, natural aging and traumatic brain cell death.

In a further embodiment, claim 8 relates to a composition comprising at least **three** of the herbal components as defined therein for use in a method of diminishing the effects of stroke or neurodegeneration in predisposed subjects or subjects at risk of stroke or neurodegeneration.

In a further embodiment, claim 9 relates to a composition comprising at least **three** of the herbal components as defined therein for use in a method of promoting cell growth.

Claim 10 concerns a composition comprising at least **one** of the components as defined therein for use in a method of treating a patient having a diseased or injured tissues of the central/peripheral nervous system and wherein the patient is also treated with a supplemental agent.

Independent claim 14 is directed to a cell culture for promoting cell growth comprising a culture medium and at least **one** of the components as depicted therein.

Claim 15 concerns at least three of the components as described therein for use in a method for inducing cell survival, growth, proliferation or differentiation of cells wherein the method comprises contacting the cells with an effective amount of said at least three components.

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

D1 WO 2007/043796 A1 (DIGITAL BIOTECH CO LTD [KR]; ILSUNG PHARMACEUTICALS CO LTD [KR]; SONG) 19 April 2007 (2007-04-19)

D2 DATABASE WPI
Week 201151
Thomson Scientific, London, GB;
AN 2011-J08612
& CN 102 091 166 A (UNIV FUDAN HUASHAN HOSPITAL) 15 June 2011 (2011-06-15)

D1 discloses a composition comprising the fraction of **Salviae miltiorrhizae** radix for treating or preventing cognitive dysfunction (cf. abstract). At page 3, section [9] and in page 13, section [173], D1 explicitly teaches the neuronal cell proliferation effects of **Salviae miltiorrhizae**.

D2 reveals a medicine comprising radix **Salviae miltiorrhizae** for promoting the regeneration of nerve muscle, for removing degenerated myelin sheath, for proliferation of schwann cells and for accelerating the regeneration of peripheral nerve after injury.

Document D3, WO 2007/106049 A1 (MOLEAC PTE LTD [SG/SG]) 20 September 2007 (2007-09-20), cited in the international search report, discloses the combined use of **rhizoma Salviae miltiorrhizae**, **radix Polygalae**, **Grassleaf sweetflag** and an agent used in western medicine, for

- the treatment of neurodegenerative diseases, stroke, brain/nervous system traumata or neuroplasticity (cf. abstract, page 2, 2nd para., 3rd para. at page 4).
- 4 The beneficial effects of at least *Salviae miltiorrhizae* for neuronal cell proliferation and for regeneration of peripheral nerve after injury are known from D1/D2. What is more, D3 discloses combinations comprising at least two or three herbal ingredients as presently encompassed, which further comprise an agent of western medicine, as well as their use in neurodegeneration according to the present application. The teaching of D3 as such clearly anticipates the subject-matter of the present application failing to comply with the requirements of novelty and inventive step pursuant to Arts. 52(1), 54(1) and 56 EPC.
 - 5 Furthermore, in a third partie's intervention (cf. letter dated 27/09/2012) according to Art. 115 EPC, novelty and inventive step of the present application are contested on the basis of prior art existing in printed books, of Ayurveda and Unani (cf. exhibits 1-5).
 - 6 General statements in the description trying to extend the scope of protection in an ambiguous way (cf. page 52 2nd para.) are to be removed (cf. in the Guidelines of the EPC, F-IV, 4.4).
 - 7 Passages in the description referring to a method of therapeutic treatment (cf. page 8, line 19ff.) should be removed or so redrafted as to indicate a possible application of the invention (Art. 53(c) EPC).