

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

Description, Pages

1-63 filed with entry into the regional phase before the EPO

Claims, Numbers

1-22 filed with entry into the regional phase before the EPO

Drawings, Sheets

1/2, 2/2 filed with entry into the regional phase before the EPO

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

D1: KUMARI M V ET AL: "Effect of "beta CATECHIN" on the life span of senescence accelerated mice (SAM-P8 strain)." BIOCHEMISTRY AND MOLECULAR BIOLOGY INTERNATIONAL APR 1997, vol. 41, no. 5, April 1997 (1997-04), pages 1005-1011, XP008111412 ISSN: 1039-9712

D2: KOMATSU M ET AL: "The efficacy of an antioxidant cocktail on lipid peroxide level and superoxide dismutase activity in aged rat brain and DNA damage in iron-induced epileptogenic foci." TOXICOLOGY 7 AUG 2000, vol. 148, no. 2-3, 7 August 2000 (2000-08-07), pages 143-148, XP008111397 ISSN: 0300-483X

D3: BUETLER TIMO M ET AL: "Green tea extract decreases muscle necrosis in mdx mice and protects against reactive oxygen species." THE AMERICAN JOURNAL OF CLINICAL NUTRITION APR 2002, vol. 75, no. 4, April 2002 (2002-04), pages 749-753, XP002459513 ISSN: 0002-9165

D4: IWAI K ET AL: "Effect of tea catechins on mitochondrial DNA 4977-bp deletions in human leucocytes" MUTATION RESEARCH, ELSEVIER, AMSTERDAM, NL, vol. 595, no. 1-2, 20 March 2006 (2006-03-20), pages 191-195, XP025250669 ISSN: 0027-5107 [retrieved on 2006-03-20]

D5: DORCHIES OLIVIER M ET AL: "Green tea extract and its major polyphenol (-)-epigallocatechin gallate improve muscle function in a mouse model for Duchenne muscular dystrophy" AMERICAN JOURNAL OF PHYSIOLOGY. CELL PHYSIOLOGY, AMERICAN PHYSIOLOGICAL SOCIETY, US, vol. 290, no. 2, 1 February 2006 (2006-02-01), pages C616-C625, XP002459514 ISSN: 0363-6143

D6: US-A-5 788 971 (TOGASAKI KEIICHI [JP]) 4 August 1998 (1998-08-04)

D7: MURASE TAKATOSHI ET AL: "Green tea extract improves running endurance in mice by stimulating lipid utilization during exercise." AMERICAN JOURNAL OF PHYSIOLOGY. REGULATORY, INTEGRATIVE AND COMPARATIVE PHYSIOLOGY JUN 2006, vol. 290, no. 6, June 2006 (2006-06), pages R1550-R1556, XP008080359 ISSN: 0363-6119

D8: US 2004/087516 A1 (ROSENBLOOM RICHARD A [US]) 6 May 2004 (2004-05-06)

D9: SINGAL A ET AL: "Green Tea Extract and Catechin Ameliorate Chronic Fatigue-Induced Oxidative Stress in Mice" JOURNAL OF MEDICINAL FOOD, MARY ANN LIEBERT, LARCHMONT, NY, US, vol. 8, no. 1, 1 January 2005 (2005-01-01), pages 47-52, XP003015493 ISSN: 1096-620X

D10: WO 2007/006135 A (H3 FORMULATIONS LTD [CA]; HEUER MARVIN A [CA]; MOLINO MICHELE [CA]) 18 January 2007 (2007-01-18)

D11: WO 2007/042271 A (DSM IP ASSETS BV [NL]; RAEDERSTORFF DANIEL [FR]; WANG-SCHMIDT YING [CH]) 19 April 2007 (2007-04-19)

D12: WO 2007/056307 A (ROIZEN MICHAEL F [US]) 18 May 2007 (2007-05-18)

D13: MOHD NAJMUL GHANI KHAN: "Hab-e-Chai Deegar Qawi Tar" KEY ATTRIBUTES OF TKDL NA4/3925, 1928, pages 1-4, XP003025360

D14: MOHD NAJMUL GHANI KHAN: "Habb-e-chai" KEY ATTRIBUTES OF TKDL NA4/3924, 1928, pages 1-3, XP003025359

D15: MOHD AKMAL KHAN: "Qahwah Bara-e-Faalij Wa Laqwa" KEY ATTRIBUTES OF TKDL AH5/2667, 2000, pages 1-3, XP003025358

D16: MOHD AKMAL KHAN: "Qahwah Deegar bara-e-Faalij Wa Laqwa" KEY ATTRIBUTES OF TKDL AH5/2668, 2000, pages 1-3, XP003025357

D17: JP 10 175858 A

D18: JP 2003 286167 A

D19: JP 2004 519241 A

D20: US 2007 149466 A1

D21: WO 01 21186 A1

D22: WO 2006 051980 A1

D23: WO 2007 020917 A1

D24: NAGASAWA T.: 'Haiyosei Kin Ishuku ni okeru Leucin Toyo ga Kokkakuhin Bunkai to Sanka Stress ni Oyobosu Eikyo (EFFECTS OF LEUCINE ADMINISTRATION ON PROTEIN DEGRADATION AND OXIDATIVE STRESS IN DISUSE MUSCLE)' REPORTS OF THE RESEARCH COMMITTEE OF ESSENTIAL AMINO ACIDS (JAPAN) vol. 175, March 2006, pages 59 - 64, XP003007861

D25: JP 2004 331724 A

D26: WO 2004 037015 A1

- 1 The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1-22 is not new in the sense of Article 54 (1), (2) and (3) EPC:
 - 1.1 D1 discloses the subject-matter of claims 1-5, i.e.that "beta CATECHIN", a preparation of natural vitamins and phytosubstances including a green tea leaf extract containing epigallo catechin gallate, has been designed as an "universal antioxidant' drink. Administration of "beta CATECHIN" increased the 50% mean survival rate by 8 weeks in case of female, and 7.5 weeks for male senescence accelerated mice (SAM).
 - 1.2 D2 discloses the subject-matter of claims 1-5, i.e.that "beta CATECHIN", a preparation of natural vitamins and phytosubstances including a green tea leaf extract containing epigallo catechin gallate, is a suitable prophylactic beverage against age - related neurological diseases associated with reactive oxygen species.
 - 1.3 D3 discloses the subject-matter of claims 1 - 10,17 - 20, i.e.that Green tea extract which contains catechins may improve muscle health by reducing or delaying necrosis in mdx mice by an antioxidant mechanism and may be an effective and non - toxic intervention strategy for persons with DMD.
 - 1.4 D4 discloses the subject-matter of claims 1 - 6,9,10,17 - 20,22, i.e. that the catechins in green tea have antioxidative and antimutagenic effects: Catechins found in tea might contribute to the maintenance of health status by reducing damage to mtDNA. Mitochondrial damage in muscular tissue due to aging is prevented.
 - 1.5 D5 discloses the subject-matter of claims 1 - 6,9,10,17 - 20,22, i.e.that Green tea extract and its major polyphenol (-) - epigallocatechin gallate improve muscle function in a mouse model for Duchenne muscular dystrophy.
 - 1.6 D6 discloses the subject-matter of claims 1 - 6,9,10,15,17 - 20, i.e.that a composition containing (a) sunflower seed extract containing chlorogenic acid; and (b) green tea leaf extract containing an epigallocatechin gallate is used to scavenge active oxygen - free radicals produced in the process of metabolism

in organisms, which are known to have relationships with inflammation, cerebral haemorrhage, arteriosclerosis, generation of cancers, destruction or weakening of cancers, radiation damage, cataracts and ageing.

- 1.7 D7 discloses the subject-matter of claims 1 - 10,16 -20, i.e.that the effects of catechin - rich green tea extract (GTE) on running endurance and energy metabolism during exercise in BALB/c mice were investigated. The endurance - improving effects of GTE were mediated, at least partly, by increased metabolic capacity and utilization of fatty acid as a source of energy in skeletal muscle during exercise. physical performance improvement is important for maintenance of quality of life in an increasingly aging society and prevent obesity related lifestyle diseases.
- 1.8 D8 discloses the subject-matter of claims 1 -6,10,16 -20, i.e. a composition comprising a flavonoid antioxidant selected from (-) - epigallocatechin, (-) - epigallocatechin - gallate, catechin, a component of green tea etc. is useful to treat peripheral neural and vascular ailments including increased muscle weakness.
- 1.9 D9 discloses the subject-matter of claims 1-5, i.e. that Green Tea Extract and Catechin Ameliorate Chronic Fatigue - Induced Oxidative Stress in Mice. These findings strongly suggest the pivotal role of oxidative stress in the pathophysiology of CFS and that GTE and catechin could be used as potential agents in the management of CFS and warrant the inclusion of GTE and catechin in the treatment regimen of CFS patients.
- 1.10 D10 discloses the subject-matter of claims 1-22, i.e.a dietary supplement (I) comprises a source of epigallocatechin gallate (A), epicatechin gallate (B), epicatechin (C), tannic acid and/or related catechins is useful for treating muscle atrophy and muscle protein wasting due to disuse, such as in the case of injury, immobilization and/or bed rest confinement, ageing and/or age - related loss of muscle mass and strength. The ompositin further comprises valine, leucine, isoleucine (branched amino acids).
- 1.11 D11 discloses the subject-matter of claims 1-10,16-20, i.e. that Epigallocatechin gallate and other catechins, found in green tea, hydroxytyrosol, resveratrol and derivatives, metabolites or their analogues are used in the manufacture of nutraceutical compositions for prevention and treatment of muscle wasting leading to muscle loss, atrophy and other associated muscle disorders in animals, in particular human.
- 1.12 D12 discloses the subject-matter of claims 1-22, i.e.a food composition useful for promoting health, supporting heart function, treating reduced defects in mitochondrial function and/or age related decline in functional capacity in

cardiovascular, nervous, immune or musculoskeletal systems comprises at least one quarter of a daily required level of each of vitamins, taurine (70 mg), green tea catechin (120 mg) and further ingredients.

- 1.13 D13 discloses the subject-matter of claims 1-5, i.e. that *Camellia sinensis* which contains catechins, is useful to treat all types of fatigue.
- 1.14 D14 discloses the subject-matter of claims 1-5, i.e. that *Camellia sinensis* which contains catechins, is useful to treat all types of fatigue.
- 1.15 D15 discloses the subject-matter of claims 9,10,19,20, i.e. that *Camellia sinensis* which contains catechins is useful to treat paralysis/hemiplegia.
- 1.16 D16 discloses the subject-matter of claims 9,10,19,20, i.e. that *Camellia sinensis* which contains catechins is useful to treat paralysis/hemiplegia.
- 1.17 D17 discloses the subject-matter of claims 1-5,9,10,19, i.e. the use of epicatechin, epigallocatechin, epicatechin gallate and/or epigallocatechin gallate to prevent disease caused by superoxide e.g. inflammation, ageing, carcinogenesis, myocardial infarction, gingivitis, periodontitis, pneumonia, senescence.
- 1.18 D18 discloses the subject-matter of claims 1-7,9,10,12,16-20 i.e. the use of (-) epigallocatechin gallate (EGCG) as active ingredient for preventing a.o. senile dementia and myasthenia gravis.
- 1.19 D19 discloses the subject-matter of claims 1-22, i.e. a food composition for preventing and restoring age related deficits e.g. for improves skeletal and cardiac muscle function (claim 19), said composition comprising tea catechins (claim 16) and taurine (claim 15).
- 1.20 D21 discloses the subject-matter of claims 1-10,16-20, i.e. compositions comprising contain fruit polyphenols as active ingredient, including catechins for inhibiting muscle atrophy in particular for disused muscle atrophy and also for treating diabetes and arteriosclerosis.
- 2 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1-D26, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC). The person skilled in the art when confronted with the problem of senescence inhibition, decreased physical endurance, fatigue, decrease in energy metabolism, mitochondrial dysfunction, muscular atrophy, prevention of a bedridden state, muscle senescence inhibition, would use a catechin either alone or in combination with a branched-chain amino-acid (known from e.g. D24 or EP1712140) or taurine (D18) without exercising inventive skills.

- 2.1 The solution proposed in claim 1-22 of the present application cannot be considered as involving an inventive step (Article 56 EPC) for the following reasons: In the absence of a special technical effect, the use, in combination, of two compounds in order to achieve a technical effect can not be considered as involving an inventive step if each of the components is known individually to achieve this same technical effect (here the treatment of a muscular disorder for which catechins and branched-chain amino acids and/or taurine are known).
- 3 It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. Should the applicant nevertheless regard some particular matter as patentable, an independent claim should be filed taking account of Rule 43(1) EPC. The applicant should also indicate how the subject-matter of the new claim differs from the state of the art and the significance thereof.
- 3.1 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 any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).
- 3.2 To meet the requirements of Rule 42(1)(b) EPC, the documents D1-D215 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.

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

Description, Pages

2-6, 13-16, 23-25, filed with entry into the regional phase before the EPO
27, 28, 33-36,
38-40, 43, 45-49,
59-63

1, 7, 8, 8a, 9-12, received on 23-08-2011 with letter of 23-08-2011
17-22, 26, 29-32,
37, 41, 42, 44,
50-58

Claims, Numbers

1-3 received on 23-08-2011 with letter of 23-08-2011

Drawings, Sheets

1/2, 2/2 filed with entry into the regional phase before the EPO

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D15: MOHD AKMAL KHAN: "Qahwah Bara-e-Faalij Wa Laqwa" KEY ATTRIBUTES OF TKDL AH5/2667, 2000, pages 1-3, XP003025358

D16: MOHD AKMAL KHAN: "Qahwah Deegar bara-e-Faalij Wa Laqwa" KEY ATTRIBUTES OF TKDL AH5/2668, 2000, pages 1-3, XP003025357

D17: JP 10 175858 A

D18: JP 2003 286167 A

D19: JP 2004 519241 A

D20: US 2007 149466 A1

D21: WO 01 21186 A1

D22: WO 2006 051980 A1

D23: WO 2007 020917 A1

D24: NAGASAWA T.: 'Haiyosei Kin Ishuku ni okeru Leucin Toyo ga Kokkakuhin Bunkai to Sanka Stress ni Oyobosu Eikyo (EFFECTS OF LEUCINE ADMINISTRATION ON PROTEIN DEGRADATION AND OXIDATIVE STRESS IN DISUSE MUSCLE)' REPORTS OF THE RESEARCH COMMITTEE OF ESSENTIAL AMINO ACIDS (JAPAN) vol. 175, March 2006, pages 59 - 64, XP003007861

D25: JP 2004 331724 A

D26: WO 2004 037015 A1

- 1 The amendment filed with the letter dated 23-08-2011 introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendment concerned is the addition of the component "a source of gypenosides". This feature has no basis in the application as filed.
- 2 Should the applicant overcome the above raised objection by deleting the term "a source of gypenosides", then the present claims would not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1-3 is not new in the sense of Article 54(1), (2) and (3) EPC:
 - 2.1 D10 discloses the subject-matter of claims 1-3, i.e. a dietary supplement (I) comprising a source of epigallocatechin gallate (A), epicatechin gallate (B), epicatechin (C), tannic acid and/or related catechins is useful for treating muscle atrophy and muscle protein wasting due to disuse, such as in the case of injury, immobilization and/or bed rest confinement, ageing and/or age - related loss of muscle mass and strength. The composition further comprises valine, leucine, isoleucine (branched amino acids).
- 3 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1-D26, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC). The person skilled in the art when confronted with the problem of inhibiting muscle senescence, in particular muscle dysfunction

or muscular atrophy, would use a catechin either alone or in combination with a branched-chain amino-acid (known from e.g. D24 or EP1712140) or taurine (D18) without exercising inventive skills.

- 3.1 The solution proposed in claim 1-3 of the present application cannot be considered as involving an inventive step (Article 56 EPC) for the following reasons: In the absence of a special technical effect, the use, in combination, of two compounds in order to achieve a technical effect can not be considered as involving an inventive step if each of the components is known individually to achieve this same technical effect (here the treatment of a muscular disorder for which catechins and branched-chain amino acids and/or taurine are known).
- 4 At least some of the objections raised above are such that there appears to be no possibility of overcoming them by amendment. Refusal of the application under Article 97(2) EPC is therefore to be expected.