

Datum
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Sheet 1
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Anmelde-Nr:
Application No: 06 771 356.0
Demande n°:

The examination is being carried out on the following application documents

Description, Pages

1-83 as published

Claims, Numbers

1-26 filed with entry into the regional phase before the EPO

1. The subject-matter of claims 1-26 concerns a method of treatment of the human body by therapy practised on the human body, which is excluded from patentability (Art. 53(c) EPC). The claims as presently formulated are thus not allowable and should be reworded in the form of a product for use in such a method according to Art. 54(4) and 54(5) EPC.

2. The following documents have been cited in the international search report; the numbering will be adhered to in the rest of the procedure.

- D1 US 2005/049284 A1
- D2 US 2002/146472 A1
- D3 US 6 838 451 B1

3. Reference is also made to the following documents, which have been cited in the supplementary European search report; the numbering will be adhered to in the rest of the procedure.

- D4 DE 196 27 344 A1 (VITASYN GMBH ENTWICKLUNG & VER [DE]) 8 January 1998 (1998-01-08)
- D5 WO 00/74662 A2 (UNIV SHEFFIELD [GB]; BUTTLE DAVID [GB]; ADCOCKS CLAIR [GB]; COLLIN PET) 14 December 2000 (2000-12-14)
- D6 WO 02/060393 A2 (THEOHARIDES THEOHARIS C [US]) 8 August 2002 (2002-08-08)
- D7 US 2002/068718 A1 (PIERCE SCOTT W [US]) 6 June 2002 (2002-06-06)

D8 WO 03/099013 A1 (OMNI NUTRACEUTICALS INC [US]) 4 December 2003
(2003-12-04)

D9 WO 94/22453 A1 (NUTRAMAX LAB INC [US]) 13 October 1994 (1994-10-13)

4. The third-party observation received on 30.06.10 pursuant to Art. 115 EPC; in particular documents

D10 Exhibit 1 - formulation AN2/324

D11 Exhibit 2 - formulation BA3/1083A

call into question the patentability of the subject-matter claimed for the reasons given below. Thus, documents D10-11 will be taken into account in the proceedings (Guid. E-V, 3) and the numbering will be adhered to in the rest of the procedure.

5. Claim 4 includes all the features of claim 1. Hence, claim 4 should be reformulated as a claim dependent on claim 1 (see Rule 43(4) EPC and Guidelines F-IV, 3.4).

6. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 5 does not involve an inventive step within the meaning of Article 56 EPC.

The use of therapeutic compositions comprising a theaflavin, for ex. in the form of a black tea extract, alone or in combination with a further (antiinflammatory) agent for treating inflammatory diseases such as e.g. arthritis is already known from D1 (claims, par. 4, 54-55), D2 (claims), D4 (claims 1, 10), D10 (par. 1, 2, 4), D11 (1, 2, 7).

Furthermore, the use of therapeutic compositions comprising glucosamine, alone or in combination with a further agent such as a flavonoid, for treating inflammatory diseases such as e.g. arthritis is already known from D5 (claims 11, 13), D6 (claims 1, 4), D3 (claim 18), D7 (claims 1, 2), D8 (claims), D9 (claim 1).

Thus, each of the ingredients presently claimed in combination as a treatment of inflammatory diseases is separately known to possess a therapeutic activity against that same disease or condition. Therefore, unless combining these compounds gives rise to an unexpected technical effect, such as synergy, or overcomes a technical

prejudice, no inventive effort is needed to arrive at the solution of providing this combination as a solution to the problem of finding a treatment for inflammatory diseases (cf. Guidelines G-VII, Annex 2.2 and 4).

However, no evidence has been provided of any such an unexpected effect or property in the present application. On p. 82-83 of the description, it is made reference to a clinical study wherein glucosamine and a black tea theaflavin extract were administered alone or as a combination to subject with osteoarthritis in the knee. The results of the study have not been provided. Also, combinations of theaflavin with other therapeutic agents were not tested in the present application. Other diseases than osteoarthritis have not been treated either.

Hence, in the absence of a surprising effect resulting from that combination, the subject-matter of claims 1, 5 does not involve an inventive step (Article 56 EPC).

Dependent claims 2-4, 6-26 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to inventive step. The features claimed in these dependent claims represent matters of common practice to a skilled person; as such, they represent mere known alternative embodiments to the therapy in question. In the absence of any indication as to a (further) technical effect being obtained by these features, the claims concerned lack an inventive step.

7. To meet the requirements of Rule 42(1)(b) EPC, D1-9 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.

8. 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.

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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 (Article 123(2) EPC).