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Anmelde-Nr:
Application No:
Demande n°:

EP2 550 970

11 759 706.2

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

Description, Pages

1-44 filed on 22-10-2012

Claims, Numbers

1-10 filed on 24-02-2014

Drawings, Sheets

1/20-20/20 filed on 22-10-2012

2 **New claims 1-10 filed by the applicant with letter of 24.02.2014 as well as third party observations filed on 09.05.2014 have been duly considered.**

3 **ARTICLE 123(2) EPC:**

The subject-matter of new claims 1-10 is not in accordance with the requirements of Art.123(2) EPC for the following reasons:

Claim 1 contravenes Art. 123(2) EPC because a pharmaceutical composition containing a paprika water extract having at least one of the effects defined as (1)(2) and (3) has not been found to be disclosed in the present application.

The applicant suggested that basis for these effects are to be found in some passages among the examples. It is however to be noted that:

- the paprika extract used in the examples is not a water extract, as claimed. In Ex.1 the paprika juice was condensed, distilled, filtered and freeze dried to obtain a powder. In Ex.2 the powder was dissolved in "saline" which seems to make reference to PBS above mentioned in the same paragraph. There is no reference whatsoever in the examples to the claimed paprika water extract
- additionally, the cited passages are directed to specific effects such as 70% IgE decrease or 70% IgG1 increase and
- these effects, expressed in relative values, are furthermore only related to a specific amount of the extract being intranasally administered to a mice model of asthma

In summary, the claimed subject-matter is neither directly and unambiguously derivable from the passages cited by the applicant nor from the application as originally filed.

Claim 2 contravenes Art.123(2) EPC because the specific treatment of asthma caused by IgE increase finds no basis in the application as originally filed.

Claim 3 contravenes Art.123(2) EPC for the same reasons which apply to claim 1. In the present application a pharmaceutical composition containing a paprika water extract having all effects defined as (1)(2) and (3) has not been disclosed.

Claims 4 and 5 contravene Art.123(2) EPC in so far they depend on claim 1.

Claim 6 contravenes Art.123(2) EPC because a health functional food containing a paprika water extract having at least one of the effects defined as (1)(2) and (3) has not been disclosed in the application as originally filed.

Claim 7 contravenes Art.123(2) EPC because the specific treatment of asthma caused by IgE increase finds no basis in the application as originally filed.

Claim 8 contravenes Art.123(2) EPC for the same reasons which apply to claim 6. In the present application a health functional food containing a paprika water extract having all effects defined as (1)(2) and (3) has not been disclosed.

Claims 9 and 10 contravene Art.123(2) EPC in so far they depend on claim 6.

4 No opinion regarding novelty and inventive step can be formulated for the subject-matter of claims 1-10 for which the requirements of Art.123(2) EPC are not fulfilled. However, for the sake of completeness and for the purpose of this communication, the following comments are made on the subject-matter of the application.

5 **FORMAT OF THE CLAIMS:**

It is to be noted that the term "for" in claims 1 and 6 is to be read as "suitable for". Therefore, compositions "for" [...] are composition as such (and not their medical use) (Guidelines F-IV, 4.13).

The attention of the applicant is drawn to the fact that the appropriate drafting of independent medical use claims according to the EPC is "Composition comprising X for use in the treatment (disease) Y".

6 **The following prior art has been taken into consideration:**

D1: XP2398899

D2: XP55071290

D3: XP5582774

D4: US20080103102

D5: XP8095205

D6: XP002702915

D7: XP002702916

D8: WO2011048221 (prior art document pursuant to Art. 54(3) EPC)

D9: XP002702917 (T-document)

D10: XP002702918

D11: Exhibit 05 provided by 3rd party observations

D1 describes the analysis of different antioxidant compounds in *Capsicum annuum* above others (whole doc).

D2 points to the use of antioxidants as therapy to control oxidative stress, which is directly associated with asthma, above other lung diseases (P.31, Col.1,§3; P.34, Col.1, §1).

D3 describes that the antioxidant activity of *Capsicum annuum* varies considerably in both genotype and maturity stages (P.7, Col.1, §1).

D4 is below described.

D5 describes that luteolin is one of the antioxidant compounds present in *Capsicum annuum* (Abstract).

D6, D7, D8 and D10 are below described.

D11 describes compositions comprising paprika (*Capsicum annuum* Linn.; cayenne pepper) for use in the treatment of bronchial asthma.

7 **LACK OF INVENTIVENESS OF THE SUBJECT-MATTER OF THE PRESENT APPLICATION**

7.1 **The closest prior art** to the subject-matter of the present application is **D4**, which describes the antiinflammatory effects of some *Capsicum annuum* isolated compounds (claims 1-2). **Pharmaceutical compositions** thereof and a **crude extract of paprika** are also described in this document (P3, §31).

7.2 **The difference** between D4 and the present application lies in the fact that the present application provides a paprika extract optionally defined as in P.5, L.20-P.6, L.10.

7.3 **In support of an inventive step**, the applicant has provided the following examples:

Ex.1. Preparation of paprika extract: paprika juice was condensed distilled, filtered and freeze dried.

Ex. 2. demonstration that the intake of the above extract modifies asthma parameters in a mice OVA model, concluding that asthma is improved by the above extract.

It is to be noted that this effect is not unexpected in view of the general knowledge at the filing date where:

- a diet rich in antioxidants was recommended for the improvement of asthma (D10)
- it was already proposed the use of antioxidants as therapy to control oxidative stress, which is directly associated with asthma (D2)
- the antioxidant effect of *Capsicum annuum* was known (D1, D3 and D5)

The skilled person would have easily come to the idea to provide paprika (i.e. an extract thereof) for the treatment of asthma.

Additionally, the anti-inflammatory effect of *Capsicum annuum* compounds was also known in the art (D4). Similarly, the skilled person would easily have come to the idea of providing paprika to treat inflammation.

In summary, the fact that the applicant quantified specific asthma parameters after the intake of the above extract and that these parameters confirm the knowledge in the art, does not involve an inventive step. In other words, the shown effect is not unexpected in view of the common general knowledge and the prior art at hand.

Additionally, the specific color of the paprika used and the form of the functional food have not been shown to have an unexpected technical effect in comparison to the composition of the closest prior art, D4.

7.4 **No unexpected technical effect can be acknowledged for the subject-matter of the present application.**

- 7.5 **The problem to be solved** "*provision of improved paprika compositions or functional foods thereof*" has not been shown to be solved. The objective technical problem needs to be reformulated to the less ambitious one "*provision of alternative paprika compositions or functional foods thereof*" for which the solutions as claimed are obvious in view of D4.
- 7.6 **It is to be noted that the same problem-solution approach would apply taking D11** as closest prior art, which furthermore directly points to the use of a composition comprising paprika for the treatment of bronchial asthma.
- 7.7 **The subject-matter of the present application is not inventive in the sense of Art. 56 EPC.**
- 8 **The Examination Division considers that the present application does not contain any subject-matter which could be regarded inventive in the sense of Art. 56 EPC. The attention of the applicant is drawn to the fact that if the above objections are not overcome, summons to attend oral proceedings will probably be issued in the next step of the procedure.**

9 **AMENDMENTS**

Care should be taken during revision not to add subject-matter which extends beyond the content of the application as originally filed (Art. 123 (2) EPC).

In order to facilitate the examination of the conformity of the amended application with the requirements of Art. 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate precisely the passages of the application as filed on which these amendments, notably new combinations of features, are based (cf. Guidelines H; CI and CII-2.2). If the applicant regards it as appropriate, this indications could be also be submitted in handwritten form on a copy of the relevant parts of the application as files.