

EP 178 1205

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

Description, Pages

2-9, 11-28	as published			
1, 1a, 10	received on	21-07-2011	with letter of	21-07-2011

Claims, Numbers

1-11	received on	21-07-2011	with letter of	21-07-2011
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Drawings, Sheets

1/6-6/6	as published
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1) With regard to the correction of the term "CLT4" to "LTC4" carried out on page 10, line 3 of the description of the application, Applicant is asked to show that the requirements of Rule 139 EPC are met, i.e. the correction must be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction.

Furthermore, on page 10 as a whole (as well as on page 9, lines 30-31 and e.g. on page 6, line 20) there are several references to "flav~~n~~oid" or "fla~~n~~v~~n~~oid", which are no scientific terms. Corrections (if any) in this regard should be made by taking special account of the requirements of Article 123 (2) EPC.

2) Applicant's arguments with regard to the objection concerning lack of inventive step of claim 8 (Article 56 EPC) have been studied thoroughly.

The Examining Division, however, would like to respectfully disagree and maintain the objection already raised previously for the reasoning as follows.

No experimental data concerning the use of an effective amount of the pure substance 5,7-Dihydroxy-2-(4-hydroxy-phenyl)-3-methoxy-chromen-4-one for treating an allergic disorder have been provided in addition or have been shown in the application itself.

Experiment 2 on page 8 to page 10 of the application, refers to the "Identification of an anti-inflammation compound". On page 10, lines 5-12 of the originally filed application, it reads that "both the ZZ Ethanol Extract and Crude Flavnoid fractions effectively reduced the CLTs and CLT4 scretion of leukemia cells tested. The fraction which showed to have the highest activity was identified to contain a major flavnoid, about 90% pure. The structure of the flavnoid was determined to be 5,7-dihydroxy-2-(4-hydroxy-phenyl)-3-methoxy-chromen-4-one (see Figure 1)."

This means, that it was found that a fraction with a **major** flavnoid, the structure of which has been determined as being 5,7-dihydroxy-2-(4-hydroxy-phenyl)-3-methoxy-chromen-4-one, reduced the CLTs and CLT4 scretion of leukemia cells tested.

Firstly, the said fraction contained also other flavnoids and further ingredients beside the major flavnoid.

Secondly, the conclusion drawn by the Applicant himself as outcome of Experiment 2 is recognizable in the bold typed title, see p. 8, lines 17-20 as well as p. 9, lines 28-29 of the application, namely that an anti-inflammation compound has been identified.

The conclusion, that also all "allergic disorders" can be treated by the pure substance (not the fraction with the major flavnoid !) is not permissible due to its mere speculative nature.

3) A Third Party Observation under Article 115 EPC was issued on 18.08.2011.

The following comments are made with respect to it.

Exhibits 2-5 refer to the use of formulations containing *Zingiber zerumbet* along with few other ingredients for the treatment of bronchial asthma. As bronchial asthma often occurs concomitantly with allergic rhinitis and as Exhibits 2-4 refer to liquid preparations and water extracts of the root of *Zingiber zerumbet* (L.) Smith, it seems that the only difference of the subject-matter of claim 1 in comparison to Exhibits 2-4 is the feature "...as the only active ingredient..." as presently claimed.

However, preassuming that the ingredients described in Exhibits 2-4 all have the same therapeutic activity (i.e. anti-bronchial asthmatic), it is not surprising that also one single component taken out of them again has the same medical efficacy. Therefore, the subject-matter of claim 1 concerning at least the use of water extracts from the root of *Zingiber zerumbet* (L.) Smith for the manufacturing of a nutraceutical formulation for treating an allergic rhinitis is not regarded as being inventive in the sense of Article 56 EPC. In this context, it is pointed out that the supplementary technical data provided by the Applicant with letter dated 13.11.2009 (Parts 1-3) refer to mixtures of an ethanol extract and a water extract from the root of *Zingiber zerumbet* and their activities against allergic asthma and allergic rhinitis, respectively.

4) As Applicant has not had a chance to submit comments with regard to the Third Party Observation, he/she is invited to do so in the light of the comments of the Examining Division as indicated above.

An informal telephone interview is not deemed to be suited to overcome the said objections. Instead, any amendments and/or arguments should be submitted in *written* form.

Applicant's auxiliary request for oral proceedings pursuant to Article 116 EPC has been acknowledged. A summons will be sent out as next step, if it is not possible to overcome the objections raised above by suitable amendments and/ or argumentation. In the latter case, a refusal of the application under Article 97 (2) EPC will have to be reckoned with.

Datum
Date 21.02.2013
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr.
Application No: 05 773 393.3
Demande n°

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

Description, Pages

2-5, 7, 8, 11-28	as published			
1, 1a	received on	21-07-2011	with letter of	21-07-2011
6, 6a, 9, 10, 10a	received on	22-03-2012	with letter of	22-03-2012

Claims, Numbers

1-7	received on	22-03-2012	with letter of	22-03-2012
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Drawings, Sheets

1/6-6/6	as published
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Claims 1-7 seem to be acceptable. Therefore, the Applicant is asked to provide carefully adapted pages of the description (Rule 42 (1) EPC). In addition, at least the brief content of the background art of **D 6** (US2002/0128273) and of **Exhibit 2** should be included in the description at the same time.