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

Description, Pages

1, 2, 4-24	as published	
3, 3a	filed in electronic form on	24-10-2012

Claims, Numbers

1-14	filed in electronic form on	24-10-2012

Drawings, Sheets

1/13-3/13, 5/13, 7/13-13/13	as published	
4/13, 6/13	filed in electronic form on	24-10-2012

The following document is cited by the Examiner. A copy of the document is annexed to the communication and the numbering will be adhered to in the rest of the procedure.

D11 JAIN AND SUMITA SRIVASTAVA S K: "Traditional uses of some Indian plants among islanders of the Indian Ocean",
INDIAN JOURNAL OF TRADITIONAL KNOWLEDGE, RESOURCES, NEW DELHI, NEW DELHI - INDIA,
vol. 4, no. 4, 1 October 2005 (2005-10-01), pages 345-357,
XP018021348,
ISSN: 0972-5938

The present communication contains remarks under the following sections:

1 Amendments (Art. 123(2) EPC)

3 Clarity (Art. 84 EPC) and sufficiency of disclosure (Art. 83 EPC)

4 Unpatentable Matter (Art. 53(c) EPC)

5 Novelty (Art. 54(1) and (2) EPC)

1 Amendments (Art. 123(2) EPC)

The following **is not** to be construed to give consent in the meaning of Rule 137(3) EPC to any future submitted amendments. It does apply to any already submitted amendment and future amendment.

Under Rule 137(4) EPC, the applicant, **when filing a set of claims**, has to provide a complete basis of the claims **in the application as filed** (where an attempt to comply with this Rule has been made, this is highly appreciated).

Referring to claims sets that are not as filed does not comply with Rule 137(4) EPC nor Art. 123(2) EPC.

A basis has to be indicated for each and every claim. The applicant should note that eg adding multiple dependencies to claims of single dependency (US-style claims) is not allowed unless there is a basis in the description as well.

Further, the content of two or more independent claims cannot freely be combined since each independent claim represents a separate embodiment.

Also, when deleting non-optional features from an independent claim then a basis has to be indicated elsewhere in the description showing that this feature was not essential, and/or that the embodiment without that feature also was encompassed by the original disclosure.

The representative is also kindly requested to indicate which single embodiment of the application as originally filed supports each resulting combination of features of the claimed subject-matter. This includes as well a justification for the omission of features of the embodiments.

Without above information, the amendments are likely to be considered as not directly and unambiguously derivable from the application as originally filed and therefore as representing added subject-matter (Article 123(2) EPC).

Any other indication in the present communication suggesting amendments to the applicant or referring to a "new set of claims" cannot be construed to give consent in the meaning of Rule 137(3) EPC to any future submitted amendments.

The entire amendments of fig. 4 and 6 violate Art. 123(2) EPC. No basis has been indicated other than that the values of the "arbitrary units" could be derived from the figures, which they cannot, particularly not with the precision of three digits. Original fig. 4 and 6 have to be re-instated.

The applicant has cited p3L28-32, p4L24-31 and p14L12-17 as a basis for the amendment of "respiratory disorders" of original claim 1 to "inflammatory respiratory disorders". None of the passages recites the term "inflammatory respiratory disorders.

p3L28-32 and p4L24-31 disclose the treatment of "asthma and other inflammatory diseases" or "inflammation and asthma".

p14L12-27 discloses that composition 1 "reduced airway inflammation", albeit in an in vivo asthma model.

There is no basis for the term of "inflammatory respiratory diseases", which violates Art. 123(2) EPC. The term has to be reverted to "respiratory disorders" selected from asthma, allergic rhinitis, hay fever, type-1 hypersensitivity and mild allergies as non-optional features - otherwise the Art. 83 EPC objection raised in the ESOP would apply again.

The applicant did not cite any basis for the term "fruit ethanol extracts derived from Aegle marmelos" of claim 1, and the Examining Division could not find any, either. Example 1 provides a basis for the term "(Aegle marmelos) Bael fruit ethanol extract", while the term employed in claim 1 encompasses an extraction process followed by a further purification ("derived"), which violates Art. 123(2) EPC. Also, the term is unclear (Art. 84 EPC) since the word "fruit" is no longer unambiguously associated with the term (Aegle marmelos) Bael and rather indicates that the ethanol employed stems from fruit fermentation. The original wording of the application should be used. Any amendment is the sole responsibility of the applicant.

Examination is based on a hypothetical claim 1 limited to Aegle marmelos Bael fruit ethanol extract.

Formal aspects

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) 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 (not of amended documents) on which these amendments are based (see Guidelines H-III, 2.2). Preferably, a copy showing all amendments accompanied by a clean typed copy should be submitted.

3 Clarity (Art. 84 EPC) and sufficiency of disclosure (Art. 83 EPC)

All objections raised in the Extended Search Opinion (ESOP) under Art. 83 and 84 EPC are herewith maintained.

The arguments and amendments submitted by the applicant on 24-10-2012 have been carefully considered, yet are not convincing since they fail to address the objections fully. It is noted that some if not the majority of objections raised previously have not been properly addressed.

In particular, the following objections are maintained under Art. 83 and/or 84 EPC (compare section III of the ESOP):

1) Lack of synergy

The applicant failed to entirely address the point of the missing concentrations. It is common erroneous practice in patent applications to test substance A at eg 5mg/mL and substance B at eg 5 mg/mL and compare it to the combination of substances A and B at 5mg/mL each, ie twice the amount of substance, and interpret any increased effect of the combination as synergy, while the combination is bound to have an additive effect at 10mg/mL total substance. In the present application, since no concentrations are given, such an error cannot be excluded. At any rate, it is impossible to add the concentrations to the application since this would violate Art. 123(2) EPC.

The applicant has added arbitrary units to fig. 4 and 6, which violate Art. 123(2) EPC (see above), and not even overcome the objection as to lack of synergy since an additive effect cannot be excluded, no error bars are provided and the effects are rather insignificant (compare ESOP).

2) Protection, control

3) Functionally defined diseases - claims 12-14

4) Adaptogens, bio-protectants, bioavailability enhancers

5) Inconciseness

6) Percentages

7) Unclear dosage

Topical conditions and wrinkles

Further, the disclosure regarding the treatment of any "topical condition" (compare claim 1) is insufficiently disclosed (Art. 83 EPC) since "topical condition" eg includes skin cancer, kaposi sarcoma, etc., which are not necessarily amenable to an anti-inflammatory treatment. Also, wrinkles are not considered to involve inflammation, which means that their treatment is insufficiently disclosed (Art. 83 EPC). Further, wrinkles are not considered a disease, which renders claim 1 unclear in that it is worded in the format required under Art. 54(5) EPC for medical uses yet refers to a non medical cosmetic use.

Adaptation of the description

The description has to be brought into conformity with the scope of the claims (Art. 84 EPC). 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).

Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. If handwritten amendments are submitted, they should be clearly legible to the printer. Preferably, a copy showing all amendments accompanied by a clean typed copy should be submitted.

4 Unpatentable Matter (Art. 53(c) EPC)

References to methods for treatment in the description should be deleted (Art. 53(c) EPC).

Claims 12-14 relate to methods for treatment of the human or animal body, which violate Art. 53(c) EPC. They would have to be reformulated into the so-called Swiss-type claim.

5 Novelty (Art. 54(1) and (2) EPC)

D1 - US2006040000 - ISR

D1 concerns an extract from Boswellia serrata that contains 30% AKBA and is distributed under the trademark 5-Loxin(R). AKBA inhibits 5-lipoxygenase. It is used to cure and control inflammatory diseases (claim 1).

§4: 5-Lipoxygenase is the target enzyme for identifying inhibitors, which have potential to cope with a variety of inflammations and hypersensitivity-based human diseases including asthma, arthritis, bowel diseases such as ulcerative colitis and circulatory disorders such as shock and ischaemia.

D4 - Arul et al., 2004 - ISR

D4 deals with Aegle marmelos leaf ethanol extracts which are used for the treatment of asthma.

D7 - Basch et al., 2004 - ISR

D7 discloses the use of Boswellia serrata extracts in asthma. The lipid-lowering effect is described as well.

The standardised boswellia products Sallaki(R) and H15(R) contain 1.4% acetyl-11-keto-beta-boswellic acid.

The standardised boswellia product S-compound(R) contains 0.7% acetyl-11-keto-beta-boswellic acid. The latter was used in the oral treatment of asthma.

The limitation of claim 1 to Aegle marmelos bael fruit ethanol extracts made it necessary to search for further art:

D11 - XP018021348 - Jain et al., 2005

According to table 1, entry 2 on p345, the fruit of Aegle marmelos is traditionally used among islanders of the Indian Ocean in the treatment of asthma. Also, on p352, it is disclosed that Aegle marmelos fruit pulp yields a refreshing drink, which is used for asthma.

6 Inventive Step (Art. 56 EPC)

Since the arguments provided by the applicant regarding synergy are not accepted, compare section 3 above, synergy is not retained for the analysis of inventive step.

The claims have been limited to a fruit ethanol extract of Aegle marmelos. Nevertheless, the objection raised in the ESOP regarding the insignificance of the in vivo data of fig. 8 and 9 is maintained and the combination of the two extracts lacks therapeutic activity (compare ESOP section VI).

The juxtaposition of AKBA-rich Boswellia serrata extract with an Aegle marmelos bael fruit ethanol extract of Aegle marmelos can be analysed in partial technical problems.

Closest prior art for the partial technical problem involving AKBA-rich Boswellia serrata extract is D1, disclosing a 30%-AKBA rich Boswellia serrata extract which can be used to treat asthma. No difference exists over the AKBA-rich extract component of claim 1. This partical technical problem is obvious over D1.

Closest prior art for the partial technical problem involving the Aegle marmelos bael fruit ethanol extract is D11, disclosing that Aegle marmelos fruit pulp can be used for the treatment of asthma, from which this component of claim 1 differs in that an ethanol extract of the fruit is used. An extract generally is concentrated in active ingredients. The partial technical problem was thus the provision of a concentrated composition for the treatment of asthma.

Ethanol extraction techniques are common general knowledge when dealing with plant material. The skilled person, starting from the Bael fruit pulp of D11, would have searched the art for providing concentrated compositions and would have come across D4 disclosing the use of an ethanol extract of Aegle marmelos leaves in the treatment of asthma. He would have immediately understood that the aim of the ethanol extraction was to concentrate active ingredients. From D11 the skilled person would have learnt that the active ingredients present in Aegle marmelos leaves could be extracted using ethanol, and would have understood that the same technique could be applied to the fruit with a reasonable expectation of success, given that often several parts of Aegle marmelos can be used for the same disease - compare the traditional use of Aegle marmelos leaves, fruit, root, bark, wood against fever as disclosed in D11, which means that similar plant metabolites can be found in the different tissues.

In consequence, the second partial technical problem lacks inventive step over the combination of D11 with D4.

Since both partial technical problems lack inventive step, the juxtaposition of claim 1 lacks inventive step.

7 Formal Aspects

To meet the requirements of Rule 42(1)(b) EPC, D1, D4, D8, D9 and D11 should be identified in the description and their relevant contents should be indicated. The applicant should ensure that it is clear from the description which features of the subject-matter of the independent claims are known from those documents.

8 Conclusion

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.