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

1-13	filed in electronic form on	17-04-2014

Drawings, Sheets

1/13-3/13, 5/13, 7/13-13/13	as published	
4/13, 6/13	filed in electronic form on	17-04-2014

The present communication contains remarks under the following sections:

1 Amendments (Art. 123(2) EPC)

Claim	Basis in the application as filed	Basis sufficient

1	claim 1 "A. marmelos Bael fruit ethanol extract": example 1 (and other examples); combination of A. marmelos fruit extract with B. serrata AKBA extract: p15§4 "topical conditions, eczema, and psoriasis": claim 5	no, see below
2	claim 13	yes
3	claims 2	yes
4	claim 14	yes
5	claim 3	yes
6	claim 4	yes
7	claim 6	yes
8	claim 7	yes
9	claim 8	yes
10	claim 9	yes
11	claims 10-12	no
12	claim 15	yes
13	claim 17	yes

Claim 1 - deletion of the term "synergistic"

The applicant has not indicated a basis under Art. 123(2) EPC for the deletion of the essential feature of synergy in claim 1 which was present in claim 1 as filed. Synergy is essential for the recognition of inventive step. Deleting an essential feature violates Art. 123(2) EPC. It has to be re-instated.

Regarding the multiple dependencies introduced to the claims filed upon entry into the regional phase, p14§5 - p18§1 provide also a basis, alongside the originally filed claims.

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). Where claims have been submitted upon entry into the European phase without indicating any basis, this **has to be made good** in any following reply from the applicant.

Referring to claims sets that are not as filed or merely stating that a basis exists in the "description as filed" or in "the original claims" does not comply with Rule 137(4) EPC nor Art. 123(2) EPC - **compare the applicant's letter received 17-04-2014, p1**.

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 original 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.

Finally, when regrouping various alternative embodiments in a single claim the applicant should refrain from what has become common yet incorrect practice, viz. to connect those alternative embodiments with an "and/or" while failing to indicate a basis for the combination of the alternatives in each permutation, ie not indicating a basis for the "and".

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 indicate consent by the Examining Division in the meaning of Rule 137(3) EPC to any future submitted amendments.

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 track change copy showing all amendments accompanied by a clean typed copy should be submitted. Handwritten amendments cannot be accepted (Rule 49(8) EPC).

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

Topical conditions and wrinkles

In the last communication, objections were raised against

- "topical conditions",

- "wrinkles".

The applicant in its letter and amendments dated 17-04-2014 did not address at all the objection raised against "topical conditions". Further, according to claim 5 as filed, "wrinkles" fall under the term "topical conditions" currently employed in claim 1, ie it is still encompassed.

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 falling under the term "topical conditions" 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.

Adaptogens, bioavailability enhancers

It is unclear to which specific compounds the terms "adaptogens, bioavailability enhancers" in claim 9 refer to. These compounds appear not to be part of the common general knowledge and are thus insufficiently disclosed (Art. 83 EPC). They have to be replaced with structurally defined compounds.

The applicant has cited in its response dated 24-10-2012 Annexes I and II which are web dictionaries with an entry for the term "adaptogen". Also cited Annex III is a review paper according to which "adaptogens are plant extracts that allow an organism to counteract adverse physical, chemical, and biological stressors by generating nonspecific resistance. Adaptogens are known to increase the availability of energy during the day, reduce stressed feelings, increase endurance, and increase mental alertness. As an example of an adaptogen Rhodiola rosea is given.

The term "**adaptogen**" is effectively a functional definition of a compound. All three following conditicns need to be fulfilled to allow a functional definition of a compound:

1) the compounds showing the desired functionality are part of the common general knowledge and the functionality is accepted in the prior art to have a clear technical meaning (see T 0241/95, OJ 2/2001, 103),

2) the functionality can be verified using tests or procedures adequately specified in the description or known to the skilled person and which do not require undue experimentation (see T 0068/85, OJ 6/1987, 228 and Guidelines F-IV, 4.10), and

3) the invention is described not only in terms of its structure, but also in terms of its function, unambiguously showing that the functional activity is essential or the solution of the technical problem underlying the invention, regardless of the structure of the compounds (Guidelines F-III, 1).

In the present case, conditions 1) - 3) have not been fulfilled for the following reasons:

1) The term "adaptogen" seems to have an accepted functionality in the world of alternative, holistic and other non-evidence based medical approaches. To "counteract adverse physical, chemical, and biological stressors by generating nonspecific resistance", or to "increase the availability of energy during the day, reduce stressed feelings, increase endurance, and increase mental alertness" which characterises an adaptogen, seem to be rather subjective parameters which can be mostly ascribed to the placebo effect occurring in a person deeply believing in the function of an adaptogen.

The "common general knowledge" in the sense of 1) has to be equated with common general knowledge evidence-based medicine since this is the only medicine which fulfills the requirements of Art. 83 EPC.

2) A placebo effect is not considered a technical feature of a medical agent and double-blind studies would reveal such a missing functionality of an adaptogen. Also, no tests to verify the function are mentioned in the application, nor are they part of the common general knowledge.

3) It is unclear how the placebo effect of an adaptogen, which is not scientifically reproducible and very much depends on the mindset of the person being treated, could be essential to the solution of the technical problem of claim 9 which is to provide a treatment for the disorders mentioned in claim 1.

The term "adaptogen" has to be deleted entirely (claims and description).

Regarding the term "**bioavailability enhancers**" of claim 9, this term also is a functional definition of a compound and the above conditions 1) - 3) have to be fulfilled.

The applicant has cited in its response dated 24-10-2012 Annexes IV, V, VI and VII and stated that "bioavailability enhancers are known to be compounds that increase the bioavailability of another compound".

Annex IV is a single patent application, unfit to disclose common general knowledge, disclosing that piperine increases the bioavailability of beta-carotene through gastrointestinal absorption.

Annex V is not a review but a single research article. Annex V discloses that docosahexanenoic acid (DHA) is a bioavailability enhancer for CYP3A substrates such as cyclosporin A when administered orally, with no effect when administered intravenously.

Annex VI is a single patent publication of which the applicant did not bother to submit anything more than the front page which bears the title "Bioavailability Enhancers". It is not the Examining Division's task to identify the meaning of this document.

Annex VII does not bear a publication date. It indicates that the web-page uses cookies, which is due to a recently (ie after the filing date in 2009) adopted European regulation which requires web-pages to inform users of the presence of cookies. It has been published after the filing date. Also, the print-out has cut off several words at the right margin, making the document partly illegible. It lists three different "bioavailability enhancers" specific for

- "poorly soluble drugs",
- "to disperse active substances and polar lipids",
- "bioavailability of today's complex compounds."

Apart from not being part of the prior art, Annex VII does not disclose in regard to which administration route which particular drugs could be enhanced in their bioavailability.

None of the Annexes IV - VII belong to documents that would disclose common general knowledge such as textbooks or widely read and cited reviews. They are single patent applications, scientific research articles and a document not forming prior art. These documents disclose:

- the route of administration is important when choosing an enhancer - DHA had no enhancing effect in the i.v. route (Annex V),

- specific drugs require specific enhancers - compare the drug / enhancer pairs of Annex IV (beta-carotene / piperine) and Annex V (cyclosporin A / DHA), or even Annex VII providing three different enhancers for different drugs.

Claim 9 refers to a mixture of two plant extracts with a multitude of unidentified compounds present. Claim 9 does not indicate of which particular compound the bioavailability should be enhanced.

The composition of the claims can be administered through many different administration routes - compare claim 10: oral, parenteral, nasal, ocular, etc. The prior art cited by the applicant discloses that the route of administration is important when choosing the enhancer for a given compound.

In the context of a mixture of many unidentified compounds to be administered through an unspecified route, and in the entire absence of any indication regarding the enhancer, the skilled person would have been represented with an undue burden selecting the appropriate bioavailability enhancer. The functional definition is thus insufficiently disclosed (Art. 83 EPC) and has to be deleted.

Regarding the three conditions 1) - 3) as indicated for the adaptogens above, conditions 2) and 3) are not fulfilled for the term of "bioavailability enhancers":

2) Unaware of the administration route and a specific compound whose absorption through administration could be measured, the skilled person could not devise any test or procedure measuring the enhancement of bioavailability.

3) No structure of any enhancer of bioavailability has been provided.

The term "bioavailability enhancers" has to be deleted entirely (claims and description).

Inconciseness / Stacked / sets of preferred features

When entering the regional phase before the EPO as designated / elected office, the applicant has considerably reduced the number of claims compared to the original claims. Claims which have various layers of preferred features stacked upon each other, or sets of different preferred features, drafted with the intention to save claims fees, are considered unclear (Art. 84 EPC). In particular, independent claims with optional features are unclear. An objection arises in particular where there is a multiplicity of alternative within a single claim, which renders it unduly burdensome to determine the matter for which protection is sought (Guidelines, F-IV, 5., Art. 84 EPC). To overcome this objection, each preferred feature has to be made the object of a dependent claim.

This objection is raised against claim 11 which is a merger of originally filed claims 10-12, wherein the latter already contained optional features which were inconcise as such (Art. 84 EPC). Claim 11 thus has up to four layers of optional features with a total of ten different groups of embodiments, each group having between 2 and many more embodiments.

Percentages

The percentages of claims 2, 4, 7 are not identified as being on a volume or weight basis, and further it is unclear whether they refer to a liquid extract of unknown concentration or on a dry substance basis. In consequence, those claims are unclear (Art. 84 EPC) and not limiting in any way.

The same objection is raised against claim 6 since it refers to "30% AKBA" while not indicating whether this is referring to a weight or dry matter concentration.

The applicant has indicated in its letter dated 24-10-2012 that the examples use weight % and thus the claims were clear. The claims are not limited through the disclosure of the examples, as the application itself sets out on p18§3 ("are not to limit the scope of the invention"). The claims have to clearly define the scope of protection sought, which is currently not the case. If the applicant believes that the examples provide a general basis under Art. 123(2) EPC, then it should limit the claims accordingly and at the same time provide a proper basis under Art. 123(2) EPC.

Also, the applicant only addressed half of the objection, viz. the "weight %" objection, but not the objection "liquid vs. dry substance", which is also maintained.

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. No handwritten amendments can be submitted (Rule 49(8) EPC). Preferably, a copy showing all amendments accompanied by a clean typed copy should be submitted.

Miscellaneous

In claim 1 the A. marmelos "extract(s) or fraction(s) or pure isolate(s)" of claim 1 as filed has been limited to "Aegle marmelos Bael fruit ethanol extract".

In relation to "Boswellia serrata", a limitation to "extract or fraction" has been made in claim 1. Dependent claims 2, 4, 7 use a different language and are thus wider in scope than claim 1, which is unclear (Art. 84 EPC).

In claim 9 there should be a comma after "anti-oxidants".

The applicant should delete all occurrences of the relative term 'about', where this term refers to a range or to range limits (Art. 84 EPC and Guidelines F-IV, 4.7).

The applicant should delete all statements similar to 'incorporated herein by reference' (Guidelines F-III, 8).

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

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

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

The third-party observation has been taken into account.

No objection.

6 Inventive Step (Art. 56 EPC)

Topical conditions, wrinkles

As a corollary to the objection raised in section 3 above with the same title, claim 1 does not sufficiently disclose a solution over the whole scope of claim 1 in relation to "topical conditions" and thus does not solve the technical problem of providing a successful treatment for those topical conditions, but only solves the less sophisticated technical problem of providing a composition comprising herbal extracts, which is immediately obvious over D1 disclosing a 30%-AKBA Boswellia serrata extract and D11 combined with D4, as set out in both the Extended Search Opinion (ESOP) and the last communication.

Other specific diseases

For the other diseases mentioned in claim 1, viz. asthma, allergic rhinitis, hay fever, type-1 hypersensitivity, mild allergies, eczema, psoriasis, the following applies:

Regarding synergy, the applicant in its latest letter dated 17-04-2014 indicated the following arguments:

Example 11

5 ug/mL of 5-loxin was tested in example 11 (Division: compare p20L1-2). On p20§3 it read "Similar experiment was also conducted with Aegle marmelos, Zingiber officinale and G. mangostana extracts.", from which it could be concluded that extracts of the latter plants were also present at 5 ug/mL of "individual ingredients".

Example 14

Example 14 referred back to example 11 stating "the experimental procedure described in Example 11 [was] repeated with composition-1 comprising 5-loxin and bael and composition comprising 5-loxin and ginger. It would be clear to the skilled person that the same concentration (5 ug/mL) and procedure was in Example 14 as in Example 11.

Examples 15 and 16 employed 10 ug/mL of the test composition or the individual ingredients and was a further indication that in example 14 composition-1 was used at 5 ug/mL only.

The applicant also discusses the results of example 15 (+ fig. 6) and example 16 (+ fig. 7), of which only example 15 is relevant since example 16 relates to Composition-2 which does not comprise Aegle marmelos but ginger extract.

The applicant stated that "clearly the results show that a greater amount of inhibition in expression of FLAP, 5-LOX and Cys-LT1 is observed" compared to the single ingredients.

The results at least supported "an improved effect (ie a different effect)".

The argument relating to the values of compositions administered in example 11 to be always 5 ug/mL can be accepted since in the description in examples 14-16 the correct approach to measure synergy was applied and this indeed seems to be the approach taken in the application.

When taking the average inhibition values for the individual ingredients in examples 11 and 14 and comparing them to the inhibition values for Composition-1 which falls within the scope of claim 1 indeed a tendency to have a greater than additive effect, which at least points to synergy.

Synergy can thus be accepted for the above named diseases.

Since synergy is a feature essential for inventive step, it has to be re-instated in claim 1 under both Art. 84 and 56 EPC, as well as under Art. 123(2) EPC (compare section 1 above).

Since the prior art does not disclose the combination and does not disclose any motivation or hint to combine the two individual ingredients of A. marmelos and Boswellia serrata extracts, and since synergy is present, an inventive step can be acknowledged.

8 Conclusion

This communication identifies patentable subject-matter. Limiting the application thereto (ie particularly overcoming all objections raised in section 3 above) would make a grant likely (Art. 97(1) EPC). Otherwise, a refusal under Art. 97(2) EPC would be the probable outcome.