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Feuille

Anmelde-Nr:
Application No: 10 781 334.7
Demande n°:

The examination is being carried out on the following application documents

Description, Paragraphs

1-42 filed with entry into the regional phase before the EPO

Claims, Numbers

1-12 filed with telefax on 27-05-2013

Drawings, Sheets

1/22-22/22 as published

The present communication contains remarks under the following sections:

- 1 **Amendments (Art. 123(2) EPC)**
- 2 **Unity of the Invention (Art. 82 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)**
- 6 **Inventive Step (Art. 56 EPC)**
- 7 **Formal Aspects**
- 8 **Conclusion**

1 Amendments (Art. 123(2) EPC)

The entire description has been re-submitted in a smaller font upon entry into the European phase. This objection was already raised in the European Search Opinion, yet the applicant did not reply at all. This Examiner refuses to analyse each page and each single word for an amendment. The representative is requested to indicate amendments to the description, if any.

The sole basis indicated by the applicant for present claims 6-12 is "the method claims". This is an inadequate indication for a basis of a claim and does not satisfy the requirements of Rule 137(4) 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 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.

In the present case, no such complete basis has been filed at any point in the proceedings and merely stating that a single feature such as fish oil of claim 1 has a basis somewhere in the description is simply not sufficient under Rule 137(4) EPC.

Referring to claims sets that are not as filed does not comply with Rule 137(4) EPC nor Art. 123(2) EPC - compare applicant's letter of 27-05-2013 - based on "the method claims".

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.

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. Handwritten amendments cannot be accepted (Rule 49(8) EPC).

2 Unity of the Invention (Art. 82 EPC)

This communication of the Examining Division is the first one in this examination proceedings raising the specific objection as regards unity of invention set out below, and thus starts the time period for filing divisional applications pursuant to Rule 36(1) (b) EPC.

In respect of the present European patent application, an objection of lack of unity was raised by the European Patent Office under Art. 82 EPC.

Only invention 1 was searched.

The Examining Division agrees with the finding of lack of unity of the subject-matter of the application for the reasons given in the Extended Search Opinion (ESOP).

The claims have been amended since the issue of the ESOP. These amended claims prima facie clearly do not overcome the non-unity objection in its entirety since they relate an invention for which no search fee has been paid, viz. invention 2 (polyunsaturated oil being fish or salmon oil). The reasons for lack of unity given in the ESOP thus still fully apply under Art. 82 EPC.

Under Rule 164(2) EPC and in line with G2/92, the application has to be limited to a searched invention (compare Guidelines, H-II, 7.2 and 7.3)

It is noted that the applicant solely stated that "the amendment of claim 1 overcomes the objection as to lack of novelty in view of document D6, thereby rend[er]ing the ex-post [facto] objection as to lack of unit[y] moot". While limiting the claims to invention 2 may indeed render the claims novel over the prior art relating to invention 1 (since invention 2 was not searched), limiting to an unsearched invention is not allowed - see above.

As the applicant has not had a search report drawn up on the other invention, the application will be prosecuted on the basis of invention 1 as indicated in the search report, viz.:

Invention 1:

A therapeutic composition comprising a **supercritical extract** (SCE) of rosemary, a **supercritical extract of oregano and a polyunsaturated oil**, and a method for treating a **cell proliferation disorder** such as prostate cancer through administration of the composition.

According to p12§1 of the present application, the polyunsaturated oil can be a seed or plant oil.

Other inventions are to be excised from the claims, description and drawings, if any. Presently, the application still lacks unity in the sense of Art. 82 EPC and the claims are unclear (Art. 84 EPC) since there is a discrepancy between the scope of the claims and the scope of the description. The subject-matter to be excised may be made the subject of one or more divisional applications according to Rule 36 EPC.

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

Only invention 1 as searched is examined.

3.1 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. 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. To overcome this objection, each preferred feature has to be made the object of a dependent claim.

This objection is raised against claims 3, 5.

3.2 Unclear three-fold ratio

Claim 3 discloses two alternatives:

- "the ratio of rosemary SCE:oregano SCE is about 2:1",
- "the ratio of rosemary SCE:oregano SCE to polyunsaturated oil ranges from 1:5 to 1:2000."

This language is unclear since the second alternative would require a three-fold ratio in the form of 1:1:5 to 1:1:2000 since three components are mentioned. The second alternative is unclear.

3.3 Insufficiently disclosed treatment of cancer

All of the examples of the present application have been carried out using a commercial formulation of only partially disclosed composition named "Wholemega", which apparently comprises salmon oil and supercritical extracts of rosemary and oregano. Nothing is disclosed comprising the extraction of the salmon oil or the precise conditions for extracting the herbs, nor are the precise contents disclosed.

The rationale behind the treatment of cancer according to the examples lies in the inhibition of COX-2 dependent cancer cells through inhibition of COX-2 (examples 7-11) using compositions comprising omega-3 polyunsaturated lipids such as EPA and DHA which compete with the omega-6 arachidonic acid (AA) for the COX and LOX enzymes, wherein the EPA and DHA tilt the balance in favour of production of non-inflammatory PGE3 and LTB5 (AA yields pro-inflammatory PGE2) (example 2).

Wholemega inhibited growth of A549 lung cancer cells which overexpress COX-2 yet failed in inhibiting the growth of H1299 cancer cells which do not overexpress COX-2 - compare fig. 17 where the "percent growth of H1299 cells" for wholemega is entirely unaffected up to 400 ug/mL of Wholemega, ie stays at above 100% without any

influence of the dose being 0, 100, 200 or 400 ug/mL, which the inventors describe as "an inhibitory effect on the proliferation of the cells" (p35L23-24), in blatant mis-interpretation of the results.

The application thus provides a sufficient disclosure only for the use of polyunsaturated oils comprising EPA and DHA for the treatment of COX-2 dependent cancers, while it provides the proof that COX-2 independent cancer cannot be treated and provides the scientific rationale that the use of a polyunsaturated oil comprising the omega-6 arachidonic acid actually increases the risk of cancer instead of lowering it.

The treatment of cancer using the composition of claim 1 is insufficiently disclosed (Art. 83 EPC) since the term "polyunsaturated oil" also encompasses oils rich in omega-6 such as olive oil, for which no activity has been demonstrated.

Diseases such as "cell proliferation disorder" (claim 6) not limited to COX-2 dependent cancers and their treatment is also insufficiently disclosed since they relate to eg benign tumours independent of COX-2, for which no evidence has been provided.

3.4 Rule 43(2) EPC

Notwithstanding the lack of unity objection above, the claims also violate Rule 43(2) EPC since they relate to

- five independent further medical use claims 6, 8-11 along the lines of Art. 54(5) EPC.

No exceptional situation exists which would justify the presence of more than one independent product claim or more than one further medical use claim, and the multitude of independent claims of those categories is characteristic of the above identified lack of unity.

When limiting the application to invention 1, only a single independent product claim and a single independent further medical use claim can be accepted under Rule 43(2) juncto Art. 84 and 82 EPC.

3.5 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).

Where a lack of unity exists or has been overcome in the claims, the description has to be limited to the chosen invention.

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.

3.6 Miscellaneous

The terms "good fats" and "bad fats" have no recognised meaning in the art and are unclear (Art. 84 EPC).

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).

The vague and imprecise statement in the description on the last page implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in a lack of clarity of the claims (Article 84 EPC) when the description is used to interpret the claims (see Guidelines F-IV, 4.4). This statement should therefore be amended to remove this inconsistency.

The proper format of a claim along the lines of Art. 54(5) EPC is "A composition for use in the treatment of..." - none of claims 6, 8-11 is formulated in that manner.

Dependent claims referring to a claim formulated along the lines of Art. 54(5) EPC have to read "The composition for use according to..." - compare claims 7 and 11, which are not formulated correctly.

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

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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.

Invention 1 as searched is examined.

The novelty objections based on documents D6 and D4 Extended Search Opinion (ESOP) have not been overcome and the majority, viz. at least claim 1, still lack novelty over those documents.

The arguments and amendments submitted by the applicant on 27-05-2013 have been carefully considered, yet since invention 1 as searched is examined, no amendments are taken into account and the assessment remains the same.

6 Inventive Step (Art. 56 EPC)

Invention 1 as searched is examined.

The inventive step objections based on document D6 raised in the ESOP have not been overcome and the claims still lack inventive step over D6.

The arguments and amendments submitted by the applicant on 27-05-2013 have been carefully considered, yet since invention 1 as searched is examined, no amendments are taken into account and the assessment remains the same.

Non-obviousness of the claimed subject-matter has to be demonstrated by defining the difference between the claimed subject matter and the teachings of D6. According to this difference the **technical problem** underlying the alleged invention has to be defined and the proposed solution (ie the subject-matter of the next set of claims) has to be demonstrated to be **non-obviously derivable from the prior art**. This should be shown eg by indicating **advantageous and unexpected properties or effects** of

the said next version of the claimed subject-matter. The argumentation in favour of inventive step should only be based on features which are actually contained in the independent claim or claims as non-optional and limiting features.

For the thus identified technical problem, in assessing the inventive step of a combination of features a feature will only be considered if the applicant has provided evidence or argued convincingly that it contributes either independently or in conjunction with one or more of the other features to the solution of said problem.

Also with regard to the thus identified technical problem, it has to be demonstrated that the proposed independent claims comprise all features essential for the inventive solution of this problem, differently expressed which are necessary to solve the technical problem with which the application is concerned.

7 Formal Aspects

To meet the requirements of Rule 42(1)(b) EPC, D4 and D6 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.