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

Description, Pages

1-57 as published

Claims, Numbers

1-10 filed with entry into the regional phase before the EPO

Drawings, Sheets

1/9-9/9 as published

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1. The amended set of claims as filed with entry into the regional phase before the EPO does not infringe the provisions of Article 123(2) EPC.

2. Documents D11-D13 are cited by the Examiner. A copy of the documents is annexed to the communication and the numbering will be adhered to in the rest of the procedure.

D11 GALIANO ROBERT D ET AL: "Topical vascular endothelial growth factor accelerates diabetic wound healing through increased angiogenesis and by mobilizing and recruiting bone marrow-derived cells.", THE AMERICAN JOURNAL OF PATHOLOGY, vol. 164, no. 6, June 2004, pages 1935-1947

D12 US 2006/287234 A1

D13 WO 2007/006484 A1

3. This communication takes into account the third-party observation received on 19.12.2013 pursuant to Article 115 EPC.

4. Present claim 1 is not correctly drafted in the form of a product for use in a method in accordance with Articles 54(4) and/or 54(5) EPC, as described in the Guidelines G-II, 4.2.Allowable claims directed to a (medical) purpose-limited product protection should therefore be drafted in the following way: "Substance/composition

for use in the treatment of ....".

Similarly, dependent claims 2-10 refer to claim 1 or any other preceding claim as if they were claims to the compound or composition per se, giving rise to an internal inconsistency, contrary to Article 84 EPC (Guidelines F-IV. 4.3 and 4.5). This objection could be overcome by rephrasing the claims as : "Substance/composition ... for use according to claim §, wherein ...".

For further processing, it will be assumed that claims 1-10 will beamended so as to be formulated in the appropriatemedical use format, in which the purpose will be taken into account for the assessment of novelty.

5. The dependency of claim 4 is wrong (Article 84 EPC). It should be made dependent on claims 1 to 2.

6. The present application appears to meet the requirements of Article 52(1) EPC because the subject-matter of claims 1-10 seems novel within the meaning of Article 54(1) and (2) EPC.

Documents D1-D3 and D5, D7-D8 all fail to disclose a pharmaceutical composition containing oleuropein as the sole active agent.

As to D4 and D6, they both disclose oleuropein as the sole active agent but not for the claimed use, namely the treatment of diabetic foot, pressure ulcer and venous ulcer.

As already explained in the international preliminary examination report drawn up for the present application in accordance with the PCT (item II), the priority (D10) is only valid for the following subject-matter : a pharmaceutical composition containing oleuropein* for use in the treatment of ulcers and wound healing, especially those in diabetic patients and/or elderly. It is also valid for said composition in the form of an aqueous gel or cream (claims 3-4), with oleuropein present at concentrations ranging from 10^{-1} to 10^{-10} or at concentration of 10^{-2}, 10^{-5} or 10^{-7}. The priority is therefore not valid for claims 1-2, claims 5-6 (in part) and claims 7-10.

* it is hereby noted that although D10 appears to test oleuropein at different concentrations in example 2 on page 16, reference is made throughout the priority document of olive leaf extracts, to which one can also add some additional products (claim 8), i.e. oleuropein is not exclusively present as the sole active ingredient.

D9 can be regarded as state of the art pursuant to Article 52(4) EPC, relevant for the assessment of novelty and inventive step for those parts of the claims not claiming a valid priority. Since D9 however only discloses oleuropein for use in the treatment of ulcers and wound healing and not for the particular treatment of diabetic foot, pressure

ulcer and venous ulcer, the subject-matter of claim 1 appears novel over D9.

7. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC.

D9, discloses oleuropein as active ingredient for use in the treatment of ulcers and wound cicatrisation. In D9, oleuropein is able to induce angiogenesis and vascularisation with a potency comparable or superior to VEGF.

According to D11, VEGF therapy is useful in the treatment of diabetic complications characterised by impaired neovascularisation. D12 actually describes VEGF to treat diabetic foot, pressure ulcer, decubitus ulcer and venous ulcer.

Also, the angiogenesis stimulating agent hyaluronic acid is known in D13 for its use in the treatment of pressure sores, vascular ulcers and diabetic foot ulcers.

Accordingly, the skilled man having knowledge of D9 combined with the teaching of D11-D13 will easily arrive at the presently claimed solution, namely to use oleuropein in the treatment of diabetic foot, pressure ulcer and venous ulcer, without the need of inventive skills.

Also, the skilled man having knowledge of the cited prior arts together with exhibits 3-5 and 9 as filed with the third-party observation received on 19.12.2013 pursuant to Article 115 EPC, he will also have an incentive to test oleuropein extracted from olea europaea Linn in the treatment of wounds and ulcers as presently claimed.

8. The applicant is requested to file new claims which take account of the above comments. When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims.

In order to comply with the requirements of Rule 137(4) 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 on which these amendments are based (see Guidelines H-III, 2.2).

In order to assist the examiner, these indications may be submitted in handwritten or typed form with tracked-changes version on an additional copy of the relevant parts of the application as filed. Such handwritten version can however in no way substitute the typed or printed clean version of the replacement pages required as from the 01 of January 2014 for all patent applications. The Applicant's attention is indeed drawn to the Notice of the EPO dated 08.11.2013 concerning the application of Rules 49 and 50 EPC and according to which, with effect from 01 January 2014, the EPO will no

longer accept **handwritten amendments** in documents replacing parts of the patent application in strict compliance with **Rule 50(1) and 49(8) EPC**.

Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).