

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

Description, Pages

1-29 as originally filed

Claims, Numbers

1-10 filed in electronic form on 17-05-2010

Drawings, Sheets

1-4 as originally filed

1. Art. 123(2) EPC

The amended claims filed in electronic form on 17-05-2010 appear to be **allowable** under **Art. 123(2) EPC**.

2. Art. 115 EPC / Rule 114 EPC

Observations by a third party have been presented with the letter dated 19/04/10 and have duly been taken into account by the Examining Division.

The documents '**Exhibit 1 to 11**' filed by the third party are considered relevant for the assessment of novelty and inventive step (Guidelines, E-VI, 3.)

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

3.1 General remark which is relevant to all claims:

It is indicated that due to the wording '... comprising chamaemeloside ...' in the independent claims 1 and 6 (due to the dependence on claim 1), the presence of other compounds is not excluded. The same applies to claim 9 regarding the wording 'the use of chamaemeloside': the presence of further components is not excluded.

Thus, a plant, parts of a plant or preparation made from a plant that comprise chamaemeloside are included in the above-mentioned wordings.

NB.: In the application, it is disclosed that 'the AP - 1 expression inhibitor of the present invention may be composed only of chamaemeloside, only of an extract of Roman chamomile or German chamomile, of a mixture of an extract of Roman chamomile and an extract of German chamomile, only of crushed product of Roman chamomile or German chamomile, of a mixture of crushed product of Roman chamomile and crushed product of German chamomile, or of a mixture thereof, or may contain additional ingredients.' (§ bridging p. 6 and 7).

3.2 Claims 8 and 9

The subject-matter of the above claims includes the features 'supplement, food, beverage, food additive, cosmetic material or cosmetic'.

For food or cosmetic preparations, the formulation as 'second medical use' - claims ('Swiss-type' claims) or a formulation in accordance with **Art. 54(5) EPC** is **not allowable**.

The nutritional or cosmetic use is not taken into account for the determination of novelty. Only the product / composition will be considered for the assessment of novelty.

The intended use will not confer novelty to the product / composition if the latter is not novel.

The subject-matter of claims 8 and 9 that relates to 'supplement, food, beverage, food additive, cosmetic material or cosmetic' is thus **not novel** as chamaemeloside or compositions comprising chamaemeloside are known in the state of the art (see for instance documents **D1** to **D12**.)

3.3 **D1**

D1 discloses that chamaemeloside has a hypoglycemic effect.

It is also disclosed that Roman chamomile is used to treat skin lesions and inflammation (see p. 612, col. 2).

Roman chamomile comprises chamaemeloside (see the present application).

Diabetes is listed among the diseases in the present claims 1, 6 and 9. It is obvious that the hypoglycemic activity of a compound is useful for the treatment of diabetes.

The Applicant argues that in contrast to the teaching of **D1**, the present application discloses a different technical effect, ie that chamaemeloside inhibits the expression of nuclear transcription factor AP-1. He cites T 836/01.

The Examining Division does not deny that the state of the art does not disclose the the inhibiting effect of chamaemeloside on the expression of nuclear transcription factor AP-1. Please see also **D1**, p. 614, col. 1, last two paragraphs above 'Conclusions' where the authors present ideas on the underlying mechanism.

The Examining Division therefore understands that the mechanism disclosed in the present application is totally different to the one disclosed in **D1** (cf the Applicant's letter of 17/05/10, p. 6, § 1-3).

! However, the new effect disclosed in the present application does **not** lead to a new clinical situation which is reflected in for instance a new sub-group of subjects being treated (in contrast to T 836/01).

The definition

wherein chamaemeloside inhibits the expression of nuclear transcription factor AP-1

only relates to the mechanism by which the effect, ie the healing of a wound or the diseases defined in claims 1, 6 or 9, ia diabetes, is achieved.

The class of patients in **D1** or the present application is the same.

Before the priority date of the present application, the medical practitioner, knowing **D1**, treated the above indications, ie for instance skin lesions and inflammation or diabetes, with chamomile or chamaemeloside (see the disclosure of **D1**).

Knowing the present application, the medical practitioner will continue to treat skin lesions and inflammation or diabetes with the known chamomile or chamaemeloside, but with the knowledge from the present application that the chamaemeloside inhibits the expression of nuclear transcription factor AP-1. Hence, the mere explanation of an effect obtained when using a compound in a known composition, even if the explanation relates to a pharmaceutical effect which was not known to be due to that compound in the known composition, cannot confer novelty on a known process if the skilled person was already aware of the occurrence of the desired effect when applying the known process.

A 'second medical use' claim wherein the 'disease' is defined in functional terms is considered to be anticipated by a prior art document which discloses the same compounds for the treatment of diseases which are also mentioned to be associated with the mechanism explained in the application, regardless of the disclosure of the mechanism in the prior art document.

The characterization of an effect, ie the prevention or the treatment of a disease by reference to the underlying mechanism cannot confer novelty to the use of a compound for the manufacture of a medicament for the prevention or the treatment of the same disease, as the function / mechanism does not change the fact that the treatment or prevention per se are already known.

With regard to the above-discussed and to item 3.1 of the present communication, the Examining Division upholds the objection that **D1 anticipates** the subject-matter of claims 1-4 and 7-10.

3.4 D2

The Examining Division refers to items 3.1 and 3.3 of this communication and therefore upholds the objection already put forward in the European Search Opinion.

As regards the mechanism, the Applicant is kindly asked to take into account the subject-matter discussed under item 3.3 for **D1** concerning this matter.

The Examining Division's view in this regards applies also to D2.

D2 discloses that chamomile flowers are used as an anti-inflammatory (p. 32, first §).

The document also discloses that chamaemeloside is comprised in chamomile (table 3).

Due to the same reasoning as was explained under items 3.1 and 3.2, **D2 anticipates** the subject-matter of the present application (inflammatory diseases are also comprised in the listed diseases, see eg claim 1).

3.5 D3 to D12:

The Examining Division refers to items 3.1 and 3.3 of this communication and therefore upholds the objection already put forward in the European Search Opinion.

As regards the mechanism, the Applicant is kindly asked to take into account the subject-matter discussed under item 3.3 for **D1** concerning this matter.

The Examining Division's view in this regards applies also to **D3** to **D12**.

D3 to **D12** disclose the usefulness of preparations of chamomile for the treatment of some of the diseases listed in eg claim 1, and thus **anticipate** the subject-matter of the present claims. Abstracts of the documents are recited in the following:

D3 discloses the usefulness of chamomile for the treatment of asthma, inflammations of skin, eczema, sun burn, acne, burns, joint inflammations, herpes, immunosuppression, psoriasis (tables 1 and 2).

D4 discloses that chamomile tea is effective in the treatment of inflammatory diseases, tumours and eczema (p. 104, col. 1).

D5 reports on an animal experiments where a mixture of herbs, comprising chamomile, was effective in inhibiting prostate cancer.

D6 reports on the antidiabetic effect of an aqueous extract of chamomile in rats (abstract, introduction and discussion).

D7 discloses the usefulness of Kamillosan Cream for the treatment of various inflammatory skin diseases (neurodermitis, dermatitis, eczema) (see the abstract, introduction and discussion).

D8 discloses the usefulness of a cream comprising chamomile grass and flowers for the treatment of psoriasis, dermatitis, urticaria, eczema and ulcers.

D9 also discloses the antiphlogistic effect of chamomile and its beneficial effect on wounds (see p. 489-490, 'Kamille').

D10 reveals that chamomile is used in traditional medicine for the treatment of hypertension and cardiac diseases (see table 1).

D11 discloses that herbal mixtures that comprise chamomile (for the preparation of tea) are effective in the treatment of chronic / allergic asthma.

D12 discloses that a herbal tea comprising chamomile is useful for the treatment of arthritis.

The subject-matter of the present claims seems therefore **anticipated** by the above-cited documents.

3.6 **D13** is not considered to destroy the novelty of the present application but discloses a link between the inhibition of expression of AP-1 and some of the diseases defined in the present claims, ie cancer, arteriosclerosis, hypertension and diabetes.

3.7 **D18** is cited by the Examiner (Guidelines C-VI, 8.2 and 8.3). A copy of the document is annexed to the communication.

Kraul, M. A., Schmidt, F.: 'Antiarthritic activity of an extract of Chamomile flowers.' Zeitschrift für die gesamte innere Medizin und ihre Grenzgebiete. 1955, 10(19), 934-936.

D18 discloses that an aqueous extract of chamomile flowers has antiphlogistic and antiarthritic effects in rats.

D18 therefore *anticipates* the subject-matter of the present application (again, see items 3.1 and 3.3)

3.8 Documents 'Exhibit 1 to 11' filed by a third party:

Exhibits 1 to 11 disclose that German chamomile from which chamaemeloside is derived has already been used alone or in combination with other ingredients for the treatment of wound healing, cancer, diabetes mellitus, arthritis, acne vulgaris and eczema through local / oral administration.

The subject-matter of the present application is thus *not novel* in the light of Exhibits 1 to 11 (see items 3.1 and 3.3 of this communication).

4. As the subject-matter of the present claims is not novel, examination of *inventive step* (**Art. 56 EPC**) will not be carried out at the moment.

However, it is indicated that the following will be relevant for the assessment of inventive step:

As regards the experimental part of the present application, it is observed that it is shown that chamaemeloside inhibits not only the expression of nuclear transcription factor AP-1 *but also the expression of NF- κ B* ('Reference Example'). It is not evident therefrom that any effect claimed is mediated by the inhibition of the expression of nuclear transcription factor AP-1.

Furthermore, the application does not comprise any information that the claimed diseases are susceptible to a treatment with an inhibitor of the expression of a nuclear transcription factor AP-1. In other words, there is no disclosure that there is a link between the diseases and nuclear transcription factor AP-1. Therefore, there is also no link between the various diseases disclosed.