

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

**Description, Pages**

1-46 as published

**Claims, Numbers**

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

**Drawings, Sheets**

1/13-13/13 as published

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**1 Lack of unity (Article 82 EPC)**

1.1 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.

1.2 The present application relates to a plurality of inventions, or groups of inventions, and therefore lacks unity within the meaning of Article 82 EPC.

The present independent claims 1-4 relate to compositions for (i) preventing damage to the skin, (ii) for treating damaged skin, (iii) for preventing a complication of a primary disorder in patients, or (iv) for preventing secondary disorders in patients having a primary disorder, wherein said damage or said complication results from oxidative damage resulting from the generation of reactive oxygen species by arNOX, said compositions comprising a processed *Narcissus tazetta* product.

On the other hand, the independent claims 5-9 pertain to compositions (i) for inhibiting the generation of reactive oxygen species by arNOX, (ii) for sequestering arNOX in a patient, (iii) for preventing a complication of a primary disorder in patients wherein said complication results from oxidative damage resulting from the generation of reactive oxygen species by arNOX,

(iv) for preventing secondary disorders in patients having a primary disorder that causes oxidative damage resulting from the generation of reactive oxygen species by arNOX, and (v) for treating damaged skin, wherein said damage results from oxidative damage resulting from the generation of reactive oxygen species by arNOX, said compositions comprising an ingredient or an active agent selected from a list consisting of the components indicated in said claims. Among all the components listed, a processed *Narcissus tazetta* product is mentioned. However, from the wording used, it appears that these compositions can also contain arNOX inhibition agents other than processed *Narcissus tazetta* products (see the components listed in said claims).

As a consequence, the present claims 5-9 propose the use of different arNOX inhibition agents as a solution to decrease the generation of reactive oxygen species, and thus to decrease oxidative damages to the skin. As such, these claims contemplate different solutions to the same technical problem, namely the use of different inhibition agents belonging to different classes of chemical compounds, forming thus an equal number of inventions.

- 1.3 According to Article 82 and Rule 44 EPC, a group of inventions is unitary if the group is linked so as to form a single general inventive concept. The link is present if there is a technical relationship between the inventions involving one or more of the same or corresponding special technical features. This special technical feature should define the contribution of the inventions over the prior art, i.e. be the reason for which the single general concept is novel and inventive.

In the present case, the claims 5-9 are directed to compositions comprising an ingredient selected from different substances or classes of substances. These substances or classes of substances as defined in said claims do not share any significant structural element, nor do they belong to the same recognized class of chemical compounds (i.e. Guidelines, C - III, 7.4.1).

In addition, no further technical feature is apparent that could be regarded as a special technical feature providing a contribution over the prior art, and thus establishing a technical relationship among the different inventions. Indeed, the special technical feature which can be attributed to these inventions or groups of inventions can be seen as being a method of inhibiting or reducing the generation of reactive oxygen species (ROS) by arNOX.

However, methods of inhibition of the arNOX activity are already known from the prior art (by using for example a ubiquinone, see the documents WO 00/57871, WO 01/72318 and WO 01/72319 cited in the application on page 2,

lines 29-31). At such, the special technical feature which links the claims does not provide a contribution over the prior art. Consequently, these separate inventions or groups of inventions are not so linked as to form a single general inventive concept. The requirement for unity of invention referred to in Article 82 EPC is therefore not fulfilled.

1.4 Accordingly, the substantive examination of the present application is limited to the subject-matter of the invention 1, namely a composition comprising a processed *Narcissus tazetta* product.

1.5 The Applicant should therefore limit the application to the invention examined and excise those parts of the application relating to the other inventions. The subject-matter to be excised may be made the subject of one or more divisional applications. The divisional applications must be filed with the European Patent Office in Munich, The Hague or Berlin and shall be filed in the language of the proceedings relating to the present application (i.e. Article 76(1) and Rule 36(2) EPC). The time limit for filing divisional applications (Rule 36(1) EPC) must be observed.

## 2 **Medical treatment (Article 53(c) EPC)**

Present independent claim 10 relates to a method for preventing damage to the skin, wherein said damage results from oxidative damage resulting from the generation of reactive oxygen species by arNOX, the method comprising administering to a patient, an amount effective to prevent said damage, a composition comprising a processed *Narcissus tazetta* product. This method allows to prevent or treat disorders caused by reactive oxygen species, and the disorders that can be treated by said method include any clinical condition in which such oxidative species have been implicated such as those listed on page 16, line 5 to page 17, line 35.

As such, the subject-matter of present independent claim 10 pertains to the use of a composition comprising a processed *Narcissus tazetta* product in a medical or prophylactic treatment of the human skin. The subject-matter of this claim concerns thus a method of treatment of the human or animal body by surgery or therapy or to a diagnostic method practised on the human or animal body.

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are to be regarded

as excluded from patentability, and therefore will not be accepted. Therapy implies the curing of a disease or malfunction of the body and covers prophylactic treatments, e.g. immunisation against a certain disease, and thus are excluded from patentability under Article 53(c) EPC.

It is to be noted that this provision does not apply to products, in particular substances or compositions, for use in any of these methods.

The claim 10 as presently formulated is thus not allowable and should be either suppressed or reworded in the form of a product for use in such a method according to Articles 54(4) and 54(5) EPC (Guidelines C-IV, 4.8).

- 3 According to the present application, the claimed compositions (see the claims 1-9) are useful in a medical method referred to in Article 53(c) EPC. Thus allowable claims directed to a medical purpose - limited protection have to be drafted pursuant to Articles 54(4) (if a first medical use is not known yet) or (5) EPC. It would then be recommended to use one of the formats mentioned in the Guidelines C - IV, 4.8 such as : "Composition for use as a medicament" or " Composition for use in the treatment of (a pathological condition)".

However, none of the present claims 1-9 is conform to said formats. As such, these claims do not meet the requirements of Article 84 EPC. Indeed, the therapeutic application of the compositions is (i) either functionally defined by a mechanism of action (i.e. by their capability of inhibiting the generation of reactive oxygen species by arNOX or sequestering arNOX), or (ii) does not define a pathological condition (disease). These definitions do not allow any practical application in the form of a defined, real treatment of a pathological condition (disease) (see Guidelines C- IV, 4.8, G 1/83 and T 0241/95, OJ 2/2001, 103).

The objection could be overcome by either introducing in the claims a list of pathological conditions (diseases) cited in the application, or by showing that means are available (in the form of experimental tests or testable criteria, either disclosed in the patent application or known from the common general knowledge), which would allow the skilled person to recognise which additional pathological conditions fall within the functional definition (Guidelines C-III, 4.22 and T 0241/95, section 3.1.1 & 3.1.2).

4 Since the present claims 1-9 are not drafted pursuant to Articles 54(4) or 54(5) EPC, the wording of these claims has to be interpreted as defining a composition comprising a processed *Narcissus tazetta* product. Indeed, the attention of the Applicant is drawn to the fact that the use of the wording "for preventing ..., for treating ..., for inhibiting ... or for sequestering ..." in present claims 1-9 has no limiting effect on the composition, as far as it does not change the physical characteristics of the composition itself. Thus, the fact that a composition of a prior art document is intended for a different use does not alter the distinguishing features, which correspond to those of the present claims (Guidelines C-III 4.13 and C-IV 9.7). As such, any composition from the prior art comprising a processed *Narcissus tazetta* product will anticipate the subject-matter of the present claims 1-9.

5 The following documents D1-D3 from the international search report and from the European search report are referred to in this communication. The numbering will be adhered to in the rest of the procedure:

D1 = JP-A-5 310549 (EPODOC or WPI abstracts)

D2 = XP-002544923

D3 = XP-002544924

6 In addition, the third-party observation dated 09.06.2009 and received on 16.06.2009 pursuant to Article 115 EPC calls into question the patentability of the subject-matter claimed for the reasons given below. Thus, the following documents D4-D7 will be taken into account in the proceedings (Guidelines E-VI, 3) and the numbering will be adhered to in the rest of the procedure.

D4 = Exhibit 1; Tila Baraae Daa-us-Salab, 1874, page 179

D5 = Exhibit 2; Dawa Nargis, 1987, page 398

D6 = Exhibit 3; Zimaad Bara-e-ganj, page 944

D7 = Exhibit 4; Tila-e-aakhar, page 35

7 The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of the present independent claims 1-9 is not new in the sense of Article 54(1) and (2) EPC for the following reasons:

Document D1 describes a skin external preparation for improving flexibility and elasticity and preventing ageing of the skin by stimulating the cells, comprising taurine and a specific galenical drug extract. The galenical drug

extract used includes an extract obtained by extracting *Narcissus tazetta* (see the epodoc or WPI abstract). As such, this preparation reads to the composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D2 relates to a cosmetic composition for improving skin appearance, such as reducing skin wrinkles, and improving aged skin, comprising abscisic acid and a derivative thereof. This abscisic acid and a derivative thereof are in the form of an extract of a plant selected from a group including *Narcissus tazetta*. Thus, in order to arrive to the presently claimed subject-matter, only one selection in one list reciting the plants is necessary. As such, this composition reads to the composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D3 discloses a skin external agent containing kojic acid or its derivatives and one or a mixture of an extract of a plant selected from a group including *Narcissus tazetta*. Consequently, in order to arrive to the presently claimed subject-matter, only one selection in one list reciting the plants is necessary. As such, this external agent reads to the composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D4 refers to a therapeutic composition containing *Narcissus tazetta* used locally for massage in the treatment of Alopecia. As such, this composition reads to the claimed composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D5 relates also to a therapeutic composition useful in the treatment of Alopecia comprising *Narcissus tazetta*. As such, this composition reads to the claimed composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D6 pertains to a therapeutic composition for local application in the treatment of Alopecia and Prurigo/Pruritus containing *Narcissus tazetta*. As such, this composition reads to the claimed composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

Document D7 describes a therapeutic formulation containing *Narcissus tazetta* used in the treatment of Leucoderma/Vitiligo and Ptyriasis Alba through local application. As such, this composition reads to the claimed composition comprising a processed *Narcissus tazetta* product according to present claims 1-9.

8 The present claims 1-9 have all been drafted as separate independent claims.

Under Article 84 EPC in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the

subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. This is however not the case in the present application.

In the further prosecution of the application, failure to file an amended set of claims which complies with Rule 43 (2) EPC, or to submit convincing arguments as to why the current set of claims does in fact comply with these provisions, may lead to refusal of the application under Article 97(2) EPC.

- 9 The document US 6,347,254 cited on page 4, line 30 of the present application seems not to be correct and should be amended.
- 10 When filing amended claims, the Applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and 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).
- 11 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123 (2) EPC, the Applicant is invited to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (Rule 137(4) EPC).