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

Description, Pages

1-18 as originally filed

Claims, Numbers

1-4 received on 12-03-2010 with letter of 12-03-2010

Drawings, Sheets

1/2, 2/2 as originally filed

1.The amendment filed with the letter dated 12.03.2010 fulfill the requirements of Article 123(2) EPC.

2.D1 and D10 do not disclose isoorientin nor rice, bamboo or aloe plant extracts.

D2 discloses compositions including isoorientin to prevent aging process affecting human skin and D3 discloses compositions including isoorientin to increase cell proliferation for wound healing.

D4 discloses a composition containing a substance having SOD-like activity and a sugar compound such as saccharified flavonoid for treating inter alia allergic diseases. However D4 does not specifically disclose isoorientin as the saccharified flavonoid.

D5 discloses isoorientin but does not disclose isoorientin isolated from aloe, bamboo or rice plant extract.

D6, D7 and D8 discloses the extracts of bamboo and rice having anti-allergic activity and an extraction method. D6 D7 and D8 do not disclose isoorientin.

The subject-matter of the present claims 1 to 4 is a pharmaceutical composition comprising isoorientin isolated from aloe, bamboo or rice plant extract for use in the prevention or treatment of allergic disease, atopic disease, skin disease, cold, hyperacidity or nervous system disorder occurred by excessive histamine.

3.Inventive step:

The examining division does not agree with the choice of D2 or D3 as the closest prior art.

The examining division is of the opinion that on the contrary D6, D7 or D8 is the closest prior art: a rice extract or a bamboo extract having anti-allergic activity.

Starting from D6, D7 or D8 the objective problem to be solved would be the identification of the active substance(s) of the extract having anti-allergic properties for the provision of a better pharmaceutical composition having anti allergic properties; (i.e the purification of the active substance having anti-allergic properties in the known plant extract.)

From Table 4 on page 15 "Effect of isoorientin on the histamine release from passively sensitized (anti-OVA antibody) lung mast cells activated by $1.0 \mu\text{g}/4 \times 10^5$ cells" it appears that the best sample are (50% ethanol extract of rind from aloe : 5.2 ∓ 0.43 in Example 3 (50 μg)) and the Bamboo extract in example 4 (100 μg) with an isoorientin content which was 3.2% : 3.2 ∓ 0.52 .

The presently claimed subject-matter does not involve an inventive step over the cited prior art, especially over the teaching of D6 or D7 or D8.

4.The third-party observation received on 21.04.2011 pursuant to Art. 115 EPC; in particular documents called exhibits taken from the Traditional Knowledge Digital Library (TKDL) in the following calls into question the patentability of the subject-matter claimed for the reasons given below. Thus, said documents 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.

In particular Traditional Knowledge digital Library (TKDL) there are several references where Aloe (Aloe barbadensis), bamboo(Bambusa arundinacea) and Rice (Oryza sativa Linn.) have been used for the treatment of bronchial asthma, Urticaria, Rhinitis, Nausea, Duodenal ulcer, Hyperacidity, Diseases of the nervous system, Inflammation, vomiting /Emesis (these are all under allergic diseases) through oral as well as local administration in the Indian system of medicine, since long. Hence, there does not seem to be any novelty or inventive step involved in the claims made in the present patent application.

The third party referred to 11 formulation names: abstracts are the following:

Exhibit 1:(pg. no.05-07) refers to a formulation containing Barbados aloe, Indian aloe, Curacao aloe, Jaffarabad aloe (Aloe barbadensis Mill.) along with few other ingredients used for the treatment of Inflammation through oral administration.

Exhibit 2:(pg. no.08-09) refers to a formulation containing Barbados aloe, Indian aloe, Curacao aloe, Jaffarabad aloe (Aloe barbadensis Mill.) as a single ingredient used for the treatment of Bronchial asthma. Mode of administration is as directed by physician

Exhibit 3:(pg. no.10-12) refers to a formulation containing Barbados aloe, Indian aloe, Curacao aloe, Jaffarabad aloe (Aloe barbadensis Mill.) along with few other ingredients used for the treatment of Urticaria through local application.

Exhibit 4:(pg. no.13-15) refers to a formulation containing Barbados aloe, Indian aloe, Curacao aloe, Jaffarabad aloe (Aloe barbadensis Mill.) along with few other ingredients used for the treatment of Vomiting / Emesis, Rhinitis through oral administration.

Exhibit 5:(pg. no. 16-18) refers to a formulation containing Barbados aloe, Indian aloe, Curacao aloe, Jaffarabad aloe (Aloe barbadensis Mill.) along with one more ingredient used for the treatment of Vomiting / Emesis, Nausea through oral administration.

Exhibit 6:(pg. no.19-22) refers to a formulation containing bamboo (Bambusa arundinacea (Retz.) Roxb. Syn.: B. bambos Voss) along with few other ingredients used for the treatment of Duodenal ulcer, Vomiting / Emesis, Rhinitis, Diseases of nervous system through oral administration.

Exhibit 7:(pg. no. 23-25) refers to a formulation containing bamboo (Bambusa arundinacea (Retz.) Roxb. Syn.: B. bambos Voss) along with few other ingredients used for the treatment of Hyperacidity through oral administration.

Exhibit 8:(pg. no.26-28) refers to a formulation containing bamboo (Bambusa arundinacea (Retz.) Roxb. Syn.: B. bambos Voss) along with few other ingredients used for the treatment of Bronchial asthma through oral administration.

Exhibit 9:(pg. no.29-31) refers to a formulation containing Rice, Paddy (Oryza sativa Linn.) as a single ingredient used for the treatment of Nausea through oral administration.

Exhibit 10:(pg. no.32-34) refers to a formulation containing Rice, Paddy (Oryza sativa Linn.) along with few other ingredients used for the treatment of Duodenal ulcer through oral administration.

Exhibit 11:(pg. no.35-37) refers to a formulation containing Rice, Paddy (Oryza sativa Linn.) along with few other ingredients used for the treatment of Vomiting / Emesis, Hyperacidity through oral administration.

The present patent application EP06716434 claims the usefulness of isoorientin isolated from aloe, bamboo or rice plant extract for the prevention or treatment of allergic diseases, atopic disease, skin disease, cold, hyperacidity or nervous system disorder occurred by excessive histamine.

However Aloe (Aloe Barbadensis) Bamboo (Bambusa arundinacea) and Rice (Oryza sativa Linn) have been used for the treatment of bronchial asthma, urticaria, Rhinitis, Nausea, Duodenal ulcer, Hyperacidity, diseases of the nervous system, through oral as well as local administration in the Indian System of medicine, since long, as it is evident from Exhibits 1 to 11.

All of these cited prior Traditional Knowledge anticipates the subject-matter of the present claims. In addition to the aforesaid references, some other references also exist in TKDL wherein Aloe, Bamboo, and Rice have been used alone or in combination with few other ingredients for the treatment of the above mentioned indications. The subject-matter of the present application is not novel nor it involves an inventive step.

5. 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.