

EP 1750651

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Sheet 1
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Anmelde-Nr:
Application No: 04 804 019.0
Demande n°:

The examination is being carried out on the following application documents

Description, Pages

1-15 as published

Claims, Numbers

1-8 filed in electronic form on 21-12-2012

1 Reference is made to the following documents, which have already been taken into consideration during these examination proceedings.

D7 DATABASE WPI
Week 200230
Thomson Scientific, London, GB;
AN 2002-248238
XP002283595,
& JP 2002 029975 A (POKKA CORP KK) 29 January 2002
(2002-01-29)

D8 "Nutrition supplement food for treating baldness, etc. - contains tahibo extracts and natural mineral",
DERWENT,
XP002263530,
and JP 9252746 A (JP 19970930 A)

Exhibit 1 "utraj",
TKDL., 1 January 1987 (1987-01-01), XP003030650,

Exhibit 2 "Sharbati Lemoon",
TKDL., 1 January 1909 (1909-01-01), XP003030651,

Exhibit 4 "Maa-ul-Jubn",
TKDL., 1 January 1909 (1909-01-01), XP003030653,

Exhibit 5 "Maajoon",
TKDL., 1 January 1928 (1928-01-01), XP003030654,

2 Article 123(2) EPC

2.1 The published application and the application documents as originally filed would appear to be identical.

- 2.2 The applicants are reminded of their obligation to state where support can be found in the published application for each and every claim and combinations of features therein. In this respect attention is directed to the "Case Law of the Boards of Appeal of the European Patent Office", 7th edition, 2013, section III.G.5.1 on page 605 in the English edition, where it is stated that "*In ex parte proceedings the applicant bears the burden of proof for the facts in his favour, e.g. ... the fact that the conditions laid down in Art. 123 EPC have been met (T 383/88)*...".
- 2.3 In their reply of 21-12-2012 the applicants have restricted themselves to explaining changes with respect to an earlier set of amended claims (page 1) and stating that the limitation to a specific flavanone is based on claim 2 and the "Results and Discussion" on page 15 of the published application (page 2).
- 2.4 However, these statements do not establish support in the published application for each and every claim and combinations of features therein. For example:
Claim 2 as published does not mention hesperetin as a possible flavanone.
The only hesperetin derivative disclosed in the published application appears to be hesperetin-7-O-glucuronide (page 15, line 4).
Claims 2 and 3 as published are each only dependent from claim 1. This means that there is no support in the published claims for the hesperidin derivatives recited in present claims 1, 2 and 3.
- 2.5 The applicants should now either state where support can be found in the published application for each and every claim and combinations of features therein or bring the claims into line with what is disclosed in the published application.
- 3 The following comments on the interpretation of independent claims 1, 2 and 3, novelty and inventive step are based on the claims filed with the applicants' reply of 21-12-2012 and are intended to assist the applicants in formulating their reply to this communication.
- 4 *Interpretation of Independent Claims 1, 2 and 3*
- 4.1 Claim 1
- 4.1.1 This is a purpose limited product claim. The effects listed in this claim can only be considered as technical features restricting the scope of protection insofar as they imply a method referred to in Article 53(c) EPC (Article 54(5) EPC).

- 4.1.2 This is only the case for the prevention and/or treatment of inflammatory skin employing compositions comprising hesperetin, hesperetin-7-O-glucuronide and hesperidin. But, even here, a claim to a composition cannot single out hesperetin, hesperetin or any of their derivatives as being responsible for the effect sought after.
- 4.1.3 On the other hand, human hair and the coat of an animal cannot become inflamed. The reference to "hair and/or coat" in claim 1 therefore does not clearly imply a method referred to in Article 53(c) EPC. In this respect attention is drawn to the effects set out at page 3, lines 2 to 9 of the description, not all of which would appear to be therapeutic in nature.
- 4.1.4 Claim 1 therefore extends to compositions *per se*.
- 4.2 Claim 2
- 4.2.1 For the applicants this is a non-medical use claim (page 1, paragraph 2 of their reply dated 21-12-2012).
- 4.2.2 However, the expression "*cytoprotection effects*" would not appear to exclude therapeutic uses on skin, hair and/or the coat of an animal. Thus, according to Wikipedia, "**Cytoprotection** is a process by which chemical compounds provide protection to cells against harmful agents."
- 4.2.3 If the applicants decide to retain this claim it should be directed to the non-therapeutic use of the specified flavanones (G 1/03 and G 2/03 in OJ EPO 2004, 413 and 448, respectively). Moreover, for the sake of clarity (Article 84 EPC), the expression "*by oral administration*" should replace "*for oral administration*" at the end of claim 2.
- 4.3 Claim 3
- 4.3.1 This is a "Swiss-type" claim. Such claims are in principle still allowable for the present application. (Guidelines G-VI, 7.1, sixth paragraph).
- 4.3.2 However, the improvements to skin, hair and/or coat conditions when hesperetin, hesperetin or any of their derivatives is orally administered to a human or pet animal do not clearly imply methods referred to in Article 53(c) EPC. Again, in this respect, attention is drawn to the effects set out at page 3, lines 2 to 9 of the description.
- 4.3.3 Claim 3 is therefore considered to extend to the manufacture of compositions comprising at least one of hesperidin, hesperetin and one of their derivatives as specified in this claim.
- 5 Exceptions to Patentability (Article 53(c) EPC)

From what has been said in section 3.2 above independent claim 2 and dependent claims 4 to 8, insofar as they are dependent on claim 2, contravene Article 53(c) EPC, insofar as they extend to therapeutic uses on skin, hair and/or the coat of an animal.

6 **Novelty (Articles 52(1) and 54(2) EPC)**

6.1 According to present page 4, lines 17 to 21: "*... flavanones compounds are found naturally in Citrus fruits, in particular in oranges, lemons and grapefruit, in their peel or pulp. Accordingly, in a first aspect, the nutritional composition may be in the form of a juice of such fruits or in the form of a concentrate. Thus, the nutritional composition may be in the form of any food product, in particular any beverage, citrus juice or any other extract from peel or pulp of citrus fruits.*". It is therefore clear that the peel, pulp and juice of citrus fruits, such as oranges, lemons and grapefruits contain hesperidin and hesperetin.

6.2 Claim 1 would therefore appear to be anticipated by orange juice containing pulp!

6.3 D7 discloses the use of lemon flavonoids and vitamin C in food or pharmaceuticals as free radical scavengers.

Although this document emphasizes the importance of the presence of the flavonoid eriocitrin in the extracts actually employed, it is quite clear that other flavonoids, including hesperidin, will also be present in these extracts (paragraph [0007] of the machine translation).

Free radicals are oxidative substances involved in tissue damage to cells and DNA, in the development of diseases, such as skin cancer and arteriosclerosis, and in ageing processes (paragraph [0007] of the machine translation).

D7 therefore detracts from the novelty of independent claims 1 and 3. Moreover, as is apparent from its machine translation, D7 also discloses the subject matter of dependent claims 4 to 8, insofar as they are dependent from claims 1 and 3.

6.4 D8 discloses the use of compositions including hesperidin, catechin and vitamin E as anti-stress substances in nutrition supplemented foods to promote blood flow, good health and for preventing hair loss or greying (paragraphs [0004] and [0010] of the machine translation).

D8 therefore detracts from the novelty of independent claims 1 and 3. Moreover, as is apparent from its machine translation, D8 also discloses the subject matter of dependent claims 4 to 8, insofar as they are dependent from claims 1 and 3.

6.5 Exhibits 1 to 6 filed with the third party observations under Article 115 EPC on 31-05-2012 disclose the use of citrus extracts containing hesperidin as active ingredient in compositions for oral consumption and for the treatment of pathological conditions as well as for cosmetic use.

Exhibit 1 mentions the use against freckles.

Exhibit 2 mentions the use against swelling of body parts.

Exhibit 4 mentions the use against inflammation, itching and freckles.

Exhibit 5 mentions the use against ageing and as hair blackener.

Exhibits 1, 2, 4 and 5 therefore detract from the novelty of independent claims 1 and 3.

7 *Inventive Step (Articles 52(1) and 56 EPC)*

7.1 As is clear from section 5 above D7, D8 and Exhibits 1, 2, 4 and 5 the use of citrus extracts containing hesperidin as active ingredient in compositions for treating the skin, hair and coat of animals by oral administration. Since the applicants have not established experimentally that hesperidin is responsible for improvements sought for the skin, hair and coat of animals, claim 2 would not appear to involve an inventive step.

7.2 On the other hand, none of the available prior art documents would appear to suggest that hesperetin and hesperetin-7-O-glucuronide are capable of reducing cell death and that hesperidin exhibits anti-inflammatory properties (example 5 on pages 1 to 15 and the results thereof on page 15 of the published application).

In this respect D7 discloses that citrus extracts based on eriocitrin and also containing hesperidin reduce tissue damage to cells, but does not identify hesperidin as an active agent for achieving this effect.

Exhibit 4 is the only document that mentions the use of citrus extracts against inflammation, but does not identify any constituent or constituents, which might be responsible for this effect.

Grant of a patent might therefore be possible on the basis of appropriate use claims based upon these results.

8 *Other Matters*

8.1 The description should be adapted to the claims (Article 84 EPC - clarity).

8.2 D7 and Exhibit 4 should be acknowledged as closest state of the art documents (Rule 42(1)(b) EPC).

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8.3 Attention is drawn to Article 123(2) EPC.