

Datum
Date 02.03.2015
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 09 832 680.4
Demande n°:

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

Description, Pages

1-28 as originally filed

Claims, Numbers

1-7 received on 22-04-2014 with letter of 22-04-2014

Drawings, Sheets

1/9-9/9 as originally filed

1. Inventive Step

The applicant has provided additional comparative tests that compare the composition of D1 with what is presently claimed, representing a composition combining D1 and D5. It is noted that the compositions of D1 and D5 are directed to the same use, and in the field of phytotherapy, it is a common approach to combine ingredients, especially if it is known that they have the same therapeutic effect. Furthermore, an additive effect can then be expected and would not justify the acknowledgement of inventive step.

The experiments listed in the description indicate that the applicant was randomly combining some of the four ingredients that are now present in claim 1.

The late filed data, comparative examples over what is disclosed in D1 and what can be expected from a combination of D1 and D4, shows that only in a few parameter a statistically significant improvement of the composition with four ingredients (i.e. Test formulation No. II) with the composition of D1 (i.e. Test formulation No. I). With respect to HDL-c level, LDL-c level, triglycerides, adiponectine, and endothelin-1, there is no statistically significant difference.

With respect to homocysteine and total cholesterol, there is a small significant difference that reflects an additive effect.

An additive effect is however what the skilled man would expect from combining D1 and D4, also taking into consideration the description where the four ingredients are randomly combined. What is shown in the late filed evidence is plausible, but also in line what the skilled man would expect from combining D1 and D4.

Datum
Date 02.03.2015
Date

Blatt
Sheet 2
Feuille

Anmelde-Nr:
Application No: 09 832 680.4
Demande n°:

In order to acknowledge inventive step, a synergistic effect, beyond what could be expected from combining ingredients and obtaining an obvious additive effect, would need to be shown.

It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. The disclosure of the prior art and the data on file would indicate that there appears to be no possibility of overcoming the inventive step objection by amendment. Refusal of the application under Article 97(2) EPC is therefore to be expected.