

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

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-10 as originally filed

The claimed subject-matter does not appear to be inventive (Article 56 EPC) in view of the teachings of the documents cited in the European Search Report and/or by Third Party for the reasoning as follows.

The problem to be solved by the application was to provide topical compositions for the treatment of osteoarthritis and related articular pathologies.

The solution, however, i.e. the combination of **a)** capsaicin or extracts containing it; **b)** boswellic acids or extracts of *Boswellia serrata* resin containing them; and **c)** escin in the free form or complexed with beta-sitosterol and/or with phospholipids or extracts of *Aesculus hippocastanum* seeds, appears to be obvious in view of the teachings of the following prior art documents.

**D 1** (Long et al.) is a systematic review of herbal medicines for the treatment of osteoarthritis: Capsaicin and *Boswellia serrata* are mentioned.

**D 2** (Meletis et al.) describes that Oleoresin gum extracts of *boswellia*, with 37.5-65% boswellic acid, exert potent anti-inflammatory actions via inhibition of proinflammatories such as leukotrienes. Other select herbs that have been used in the treatment of rheumatoid arthritis (RA) include cayenne (*capsicum frutescens*) etc..

In **D 3** (Menvielle-Bourg) *Boswellia carterii*, *Boswellia serrata* (Oliban) and Cayenne (*Capsicum frutescens*) are listed as active against rheumatism, arthrose, neuropathy.

**D 4** (Guillemin et al.) already shows that Escin (as Reparil solution and gel) is useful for the treatment of lipodystrophies and chronic tissue edema (arthrose).

**D 5** (Clayton) mentions *Boswellia* (guggulu) and Horse-Chestnut seed as Nutraceuticals used in the management of Osteoarthritis.

D 6 (Stycynski) reports that degenerative stenosis is caused by disc degeneration, osteoarthritis of the facet joint and hypertrophy of the ligamentum falvum. The author found satisfactory results of conservative treatment by using such medication as Aescin (alpha - *Escinum amorphicum*) etc..

Furthermore, there are several references where *Boswellia serrata* and *Aesculus hippocastanum* have been used for the treatment of osteoarthritis, inflammation of joints or as an anti-inflammatory agent through the local application in the Indian systems of medicine since long, as is evident from Exhibits 1 to 3 cited by Third Party under Article 115 EPC, namely:

Exhibit 1 (RS21/356A) already shows a therapeutic composition comprising *Boswellia serrata* (formulated as paste for local application) for use in the treatment of osteoarthritis.

Exhibit 2 (RS22/1127) refers to a formulation containing *Boswellia serrata* along with few other ingredients useful in the treatment of inflammation through local application.

Exhibit 3 (MH3/495P) relates to a formulation containing *Aesculus hippocastanum* as single ingredient used as anti-inflammatory agent through local application.

Hence, to sum up, each of the components a, b, c of the topical composition of claim 1 was already known in the prior art as being useful for treating osteoarthritis or related articular pathologies.

Therefore, as long as no surprising/unexpected effect of the combination of a+b+c (, which must be superior to a merely additive effect) is shown, inventive merits in the sense of Article 56 EPC cannot be acknowledged.

The above mentioned objections should be overcome by suitable amendment or explanation. If not, refusal of the application (Art. 97 (2) EPC) should be expected.

In the case where new claims are filed, they should be accompanied by carefully adapted pages of the description (Rule 42 (1) EPC).