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

Description, Pages

1-12	as originally filed				

Claims, Numbers

1-7	received on	12-09-2014	with letter of		12-09-2014

Drawings, Sheets

1/2, 2/2	as originally filed

1) Applicant has submitted an Annex I (enclosed to Applicant's letter of 12.09.2014) ("Study on effect of *astragalus* soup and its components to liver fibrosis model of DMN-induced rat") in order to provide experimental data to verify the alleged synergistic effect of *Astragalus* Astragalosides and Glycyrrhiza Acid for use in treating chronic liver diseases (claim 1), or liver fibrosis (claim 2) or liver cirrhosis (claim 3), and to submit evidence for the alleged inventive merits. However, in this regard, Applicant firstly is asked to provide a translation of the said attached document.

Secondly, as far as it is evident from Applicant's brief discussion of the results of this annexed document, the reductions of appearance of ascites are not clearly linked/ associated to the (underlined) three medical/therapeutic indications according to claims 1, 2, 3. Therefore, for the time being, these results cannot be taken into consideration and so far a synergistic effect concerning the three separate medical indications of claims 1, 2 or 3 has not yet been proved.

In this respect, Applicant's attention is drawn also to the fact, that the embodiments and examples in the description of the present application (page 5 - page 12) relate to liver *fibrosis* only, whereas claims 1 and 3 indicate other (liver) disorders, namely "chronic liver diseases" or "liver cirrhosis", respectively. For these indications, experimental data are still missing.

2) A 'Third Party Observation' under Article 115 EPC has been filed (on 03/06/2014), where prior art documents have been provided which already report on formulations containing *Astragalus* gummifer and *Glycyrrhiza glabra* L. in combination for the treatment of liver diseases such as hepatitis, hepatosis, hepatic diarrhoea or hepatic obstruction (Exhibits 1-5).

Also **D 1** (WPI abstract of CN101744869) already reports on a traditional Chinese medicinal compound extract composition used for e.g. improving pathological functions of pancreas and hepatic tissue, comprising Radix *Astragali* and *Licorice* water extract, and glycyrrhizic acid as well as various astragalosides and several other ingredients.

However, inventive merits in the sense of Article 56 EPC are not recognizable for the reasons as following. The problem(s) to be solved by the present application was/were to find pharmaceutical compositions for treating chronic liver diseases (claim 1), for treating liver fibrosis (claim 2) and for treating liver cirrhosis (claim 3).

The solution as claimed, i.e. the combination of *Astragalus* Astragalosides and Glycyrrhiza Acid, is considered as being obvious for the reasons as already outlined in detail previously e.g. in the opinion associated with the supplementary European search report.

The Applicant starts from **D 5** as closest prior art which already reports on protective effects of astragaloside IV on porcine-serum-induced hepatic fibrosis in rats and *in vitro* effects on hepatic stellate cells. As already pointed out, **D 6-D 8** already describe glycyrrhizic acid alone as being useful for the treatment of hepatic diseases such as hepatitis.

Therefore, due to lack of a proved synergistic effect in treating chronic liver diseases or liver fibrosis or liver cirrhosis, of a pharmaceutical composition consisting of *Astragalus* Astragalosides and Glycyrrhiza Acid, the skilled person would simply aggregate two known active agents which have already been shown to be effective in the same medical field, as long as no surprising/unexpected effect has been made plausible.

3) 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).