

1 **Notice**

Applicant is respectfully notified of a change in the composition of the examining division

2 **Documents on file**

As originally filed (divisional): description pages 1-95 and drawings sheets 1-21

Filed on 5.10.2011: claims 1-17

3 **Nomenclature**

Withania somnifera = ashwagandha, indian ginseng, poison goosberry, winter cherry.

Solanaceae

Curcuma longa = turmeric, haldi; Zinziberaceae

Bacopa monnieri = water hyssop, brahmi, thyme-leafed gratiola, herb of grace, indian pennyworth; Plantaginaceae.

Silybum marianum = cardus marianus, milk thistle, blessed milk thistle, Marian Thistle, Mary Thistle, Saint Mary's Thistle, Mediterranean milk thistle, variegated thistle, Scotch thistle;

Asteraceae

Camellia sinensis = green tea; theaeae;

Centella asiatica = gotu kola; mandukparni, indian pennywort, marsh pennywort, Luei gong gen, brahmi; Apiaceae.

Ginkgo biloba = ginko, ginkgo, ginnan; Ginkgoaceae

Aloe vera = aloe vera, aloe barbadensis Mill.; Aloeaceae

N-acetyl cysteine = NAC

4 **Further citations**

D5 WO02/100329

D6 WO03/006034

D7 Scartezzini (2000); J. Ethnopharm. 71:23-43

D8 Bhattacharya (2001); J. Ethnopharm. 74:1-6

D9 Bhattacharya (2000); Phytother. Res. 14:174-179

D10 Soto (2003); Comp. Biochem. Physiol., C136:205-212

- D11 Rietveld (2003); J. Nutr. 133:3285S-3292S
D12 Chaudhary (2004); J. Tissue Res. 4(1):113-115
D13 Goh (2002); Food Res. Intl.35:815-820
D14 McCarthy (2001); Meat Sci, 58(1):45-52
D15 Odetti (2003); Diabetes 52:499-505
D16 Nelson (2006); Free Radical Biol & Med. 40:341-347

5 **Art. 54, 56**

D5 discloses compositions for use in treating the effects of aging (through antioxidative activity). The composition of example 9 contains aswaghand, turmeric, green tea, NAC, and ginkgo D5 anticipates or directly renders obvious the subject-matter of claims 1-12, 13, 15-17

D6 discloses compositions for use in treating cancer. The composition contains Withania, turmeric and aloe, all herbs known to have antioxidative effect. D6 anticipates or directly renders obvious the subject-matter of at least claims 1-11, 13, 15-17

Claim 14. Antioxidant herbal compositions are known in the closest prior art (eg D5), as are their medical uses (eg D6, not to mention innumerable Rasayana ayurvedic formulations. The difference lies in the choice of herbs. There is no special technical effect shown in the application as filed other than antioxidative activity. The problem is to provide other antioxidative compositions. The solution is a composition with turmeric, milk thistle, and another component. However, it is known from prior art that ashwagandha (D7, D8), turmeric (D7), Bacopa (D9), milk thistle (D10), green tea (D11, D14), gotu kola (D12). Ginko (D13), aloe vera (D14) and N-acetyl cysteine (D15) have antioxidant properties. It is even known (as acknowledged in D16, pg342L end) that they have SOD inducing properties and clear TBARS. **Moreover, all are known as safe herbs and have been used for centuries in ayurvedic medicine (see third party observations).** In the absence of a specific effect (and therefore an inventive reason) for choosing one or more of these ingredients, making a composition of known antioxidants is a mere juxtaposition of technical features with known effects, with the hope of having an additive effect (see D16). This is not inventive.

6 **Art. 82**

The claims cover several **embodiments**. In order to be considered as a single invention, the **embodiments** must share **at least one technical feature that is novel and inventive**. In view of the teachings of the prior art, I **struggle to find any** such common feature. Therefore, the **embodiments claimed are not so linked as to form a single, general inventive concept**. The **application lacks unity - but since none of the claims currently on file are allowable, I will not insist further on this matter for the time being.**

Art.83, 84

a) Some results are shown in terms of increase in SOD activity, reduction of TBARS levels, and levels of oxidation. These were obtained only with the protandim compositions, NOT with the individual herbs. The generic claims to composition of 3 herbs (or their extracts) selected from the group are not supported.

Note: there is a "squeeze" situation. If it were argued that "obviously they work" given the knowledge of prior art, then the finding of lack of inventive step is reinforced. If in defence of inventive step it were argued that "the effect of the mixture is unpredictable", then the generic claims are not supported.

b) The data concern Protandim, which are specific composition of herb *extracts* in specific ratios. A technical effect for the wide ranges implied in the claims is not supported by the data. More precision is required, in view of the notoriety of herbal remedies, whose potency and effectiveness vastly depend on standardization and quality of the extracts.

c) The data on file might justify a claim to compositions for use in reducing or preventing oxidative injury. There is no evidence whatsoever that this is enough to treat cancer or the other conditions listed in claims 11, 16. There is lack of support and disclosure.

7 Conclusions

The claims 1-17 presently on file do not meet the requirements of the EPC.

Applicant is cordially invited to submit suitable amendments. A table of correspondence showing the basis for the claims in the parent application (WO2005/094862) should be provided in accordance with Rule 137(4).

Applicant should be mindful of Rule 137(3), which will be applied strictly.