CLAIMS

What is claimed is:

1. A biological analysis method of evaluating the quality and potential *in vivo* activity of a test batch of an herbal composition, the method ~~comprising~~consisting of:

(a) subjecting the test batch of the herbal composition to a signaling transduction activity response assay that comprises measuring the signal transduction activity response against one or more signaling pathways selected from the group consisting of TNF-alpha-NF-kappa-B, TLR2-NF-kappa-B, TLR4-NF-kappa-B, IL6-stat3, IFN-gamma-STAT1/ STAT2, IFN-alpha-STAT1/ STAT2, DEX-GR, COX-2, iNOS, NRF2, TGF-beta-Smad2/3, TPA-AP1, CREB, wnt3a-Lef/b-cat, VD3-VDR, ER-alpha, ER-beta, DHT-AR and aldosterone-MR; and/or

(b) subjecting the test batch of the herbal composition to a gene expression assay that comprises measuring one or more protein-encoding genes selected from the group consisting of ICAM, IRF5, AKR1C1, HO1, GCLM, Axin2, BHMT2, CD24, and KRT23;

comparing the test batch results of the biological analysis method with results derived from a known batch of an herbal composition which has a known level of *in vivo* activity;

~~wherein a measurement of the difference between the test batch results and the known batch results provides an evaluation of the quality and potential *in vivo* activity of the test batch herbal composition~~

wherein the herbal composition comprises one or more compositions selected from the group consisting of herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z), any fractions thereof and any active chemicals present in the herbal extracts or fractions thereof.

~~2. The method of claim 1, wherein the herbal composition comprises one or more compositions selected from the group consisting of herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z), any fractions thereof and any active chemicals present in the herbal extracts or fractions thereof.~~

2~~3~~. The method of claim 1~~2~~, wherein the herbal composition is PHY906, wherein PHY906 comprises herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza*

*uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z) in a 3 : 2 : 2 : 2 (S : G : P : Z) ratio.

34. The method of claim 1, wherein the signal transduction activity response assay comprises one or more assays selected from the group consisting of luciferase reporter assays and enzymatic assays.

45. The method of claim 1, wherein if the test batch results are between 90% and 110% of the known batch results then the test batch is determined to have sufficiently similar quality as the known batch and potential *in vivo* activity.

~~6. The method of claim 1, wherein the quality of the test batch of the herbal composition is further analyzed by LC-MS.~~

57. A biological analysis method of evaluating the quality and potential *in vivo* efficacy of a test batch of PHY906 by subjecting the herbal composition to a signaling transduction activity response assay that comprises measuring the signal transduction activity response against one or more signaling pathways selected from the group consisting of TNF-alpha-NF-kappa-B, TLR2-NF-kappa-B, TLR4-NF-kappa-B, IL6-stat3, IFN-gamma-STAT1/ STAT2, IFN-alpha-STAT1/ STAT2, DEX-GR, COX-2, iNOS, NRF2, TGF-beta-Smad2/3, TPA-AP1, CREB, wnt3a-Lef/b-cat, VD3-VDR, ER-alpha, ER-beta, DHT-AR and aldosterone-MR; and

comparing the results of the biological analysis method with results derived from a known batch of PHY906 which has a known level of *in vivo* activity;

wherein a measurement of the difference between the test batch results and the known batch results provides an evaluation of the quality and potential *in vivo* activity of the test batch herbal composition.

~~8. Use of a test batch of PHY906 which shows similar activity in a biological analysis method compared to a known batch of PHY906 which has a known level of *in vivo* activity, in the manufacture of a medicament for the treatment of cancer, wherein the biological analysis method comprises:~~

~~a signaling transduction activity response (STAR) assay that comprises measuring the signal transduction activity response against one or more signaling pathways~~

~~selected from the group consisting of TNF-alpha-NF-kappa-B, TLR2-NF-kappa-B, TLR4-NF-kappa-B, IL6-stat3, IFN-gamma-STAT1/ STAT2, IFN-alpha-STAT1/ STAT2, DEX-GR, COX-2, iNOS, NRF2, TGF-beta-Smad2/3, TPA-AP1, CREB, wnt3a-Lef/b-cat, VD3-VDR, ER-alpha, ER-beta, DHT-AR and aldosterone-MR; and~~

~~comparing the results of the STAR assay with results derived from the known batch of PHY906.~~

6. The method of claim 5, wherein the herbal composition comprises herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z).

7. The method of claim 5, wherein the signal transduction activity response assay comprises one or more assays selected from the group consisting of luciferase reporter assays and enzymatic assays.

8. The method of claim 5, wherein if the test batch results are between 90% and 110% of the known batch results then the test batch is determined to have sufficiently similar quality as the known batch and potential *in vivo* activity.