(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 February 2012 (09.02.2012)

PCT

(10) International Publication Number
WO 2012/018370 A4

(51) International Patent Classification:
A01N 65/00 (2009.01) *A61K 36/00* (2006.01)

(21) International Application Number:
PCT/US2011/001314

(22) International Filing Date:
25 July 2011 (25.07.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/400,787 2 August 2010 (02.08.2010) US
13/135,616 11 July 2011 (11.07.2011) US

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) **Title**: ANTICANCER AND IMMUNOMODULATING MOLECULES AND FRACTIONS CONTAINING SAID MOLECULES

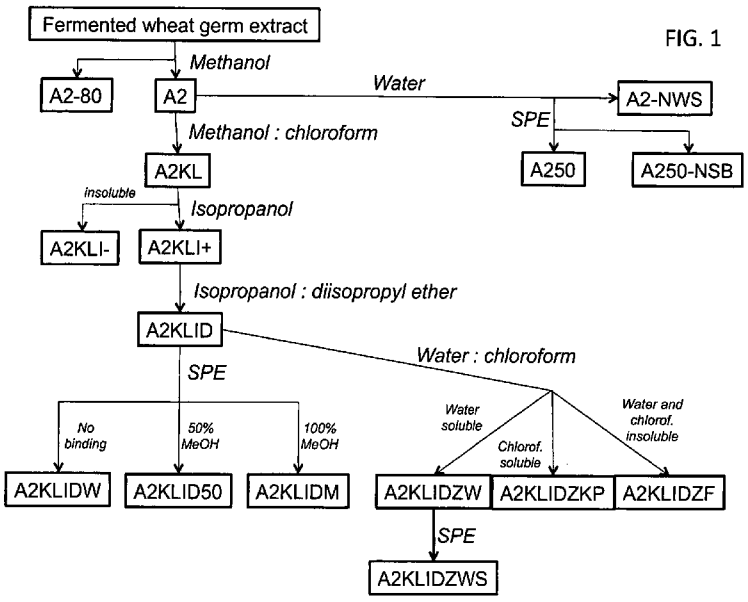

FIG. 1

(57) **Abstract**: Biologically active substances and fractions of wheat germ ferment/ fermented wheat germ extract (FWGE), including formulation A250, the processes for their production, the pharmaceutical preparations containing them, and their uses.

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Published:

— *with international search report (Art. 21(3))*

— *with amended claims (Art. 19(1))*

Date of publication of the amended claims: 12 April 2012

AMENDED CLAIMS
received by the International Bureau on 1 Feb. 2012 (01.02.2012)

WE CLAIM:

1. A pharmacological formulation A250 having anti-cancer, immuno-modulatory, metabolic-regulatory, dietary supplement, and medical or dietary-food properties, wherein said formulation A250 is obtained from fraction A2 of fermented wheat germ extract (FWGE), said fraction A2 being obtained by alcoholic extraction of said FWGE.

2. The formulation A250 of Claim 1, wherein said formulation is characterized by its high-performance liquid chromatography (HPLC) fingerprint UV chromatogram.

3. The formulation A250 of Claim 1, wherein said formulation is fabricated into a delivery modality.

4. A method of synthesizing a formulation A250 having anti-cancer, immuno-modulatory, metabolic-regulatory, dietary supplement, and medical or dietary food properties, wherein said formulation is obtained from fraction A2 of fermented wheat germ extract (FWGE), said fraction A2 being obtained by alcoholic extraction of said FWGE.

5. The formulation A250 of Claim 4, wherein said formulation is obtained by dissolving said fraction A2 in water, separating by solid phase extraction (SPE), and eluting the stationary phase by alcohol and drying the ~~said~~ alcoholic solution.

6. The formulation A250 of Claim 4, wherein said formulation is obtained by dissolving said FWGE in alcohol, filtering, cooling down the resulting filtrate, filtering, evaporating a resulting alcoholic solution, dissolving the resulting dry material in water, separating by solid phase extraction (SPE), eluting the stationary phase by alcohol and drying said alcoholic solution.

7. The formulation A250 of Claim 4, wherein said formulation A250 is obtained by mixing alcohol into wheat germ fermentation broth concentrate, filtering the mixture, removing

the alcohol from the filtrate, filtering the resulting aqueous phase, separating by solid phase extraction (SPE), eluting the stationary phase by alcohol and drying ~~the~~ a resulting solution.

8. A method of synthesizing biologically active formulation A250 and fractions A2-80, A2-NWS, A250-NSB, A2KL, A2KLI-, A2KLI+, A2KLID, A2KLIDW, A2KLID50, A2KLIDM, A2KLIDZW, A2KLIDZWS, A2KLIDZKP and A2KLIDZP obtained from fraction A2 of fermented wheat germ extract (FWGE), including the steps of

a. Separating said formulation A250 or said fraction A2KL from said fraction A2, and

b. Fractionating said fraction A2KL to obtain fractions A2KLI-, A2KLI+, A2KLID, A2KLIDW, A2KLID50, A2KLIDM, A2KLIDZW, A2KLIDZWS, A2KLIDZKP and A2KLIDZP.

9. Process of Claims 5-7, wherein the alcohol used as solvent is aliphatic alcohol with 1-alpha carbon atom, preferably methanol or ethanol, more preferably methanol.

10. Process of Claims 5-7, wherein the stationary phase for solid phase extraction (SPE) is a polymer, preferably a silicon derivative with carbon chains.

11. Process of Claims 5-7, wherein the alcohol used as eluent for solid phase extraction (SPE) is aliphatic alcohol with 1-alpha carbon atoms, preferably methanol or ethanol, more preferably methanol.

12. Process of Claims 5-7, wherein drying is by vacuum-evaporation, preferably vacuum-drying, more preferably vacuum-drying and lyophilization.

13. A pharmaceutical preparation containing as active ingredient the formulation A250 of Claim 1.

14. A pharmaceutical preparation of Claim 13, wherein the formulation A250 is formulated in forms of tablets, coated tablets, dragées, coated dragées, granules, sachets, capsules, suspension, emulsion, spray, suppository, ointment, patch, liposome.

15. The use of the formulation A250 of Claim 1 for the production of pharmaceutical preparations having anti-cancer and/or immune-modulatory and/or metabolic-regulatory properties.

16. The use of the formulation A250 of Claim 1 for the production of dietary supplement, medical food or dietary food for special medical purpose for mammals, respectively.

17. A method of preventing and/or inhibiting the development, growth and/or dissemination of cancer in mammals, characterized by administering to a subject an effective amount of a pharmaceutical preparation comprising the formulation A250 of Claim 1.

18. A method of preventing and/or treating immunological diseases and/or metabolic imbalances in mammals, characterized by administering to a subject an effective amount of a pharmaceutical preparation comprising the formulation A250 of Claim 1.

19. The method of Claim 17, wherein the cancer is correlated with the activity of kinases belonging to any of the following kinase family subclasses: CAMK (Calcium dependent kinases), CMGC (cyclin dependent kinases), TK (Tyrosine Kinases) and AGC (cAMP kinases).

20. The method of Claim 18, wherein the immunological disease and/or the metabolic imbalance is correlated with the activity of kinases belonging to any of the following kinase family subclasses: CAMK (Calcium dependent kinases), CMGC (cyclin dependent kinases), TK (Tyrosine Kinases) and AGC (cAMP kinases).

21. A method of standardizing and/or quality controlling the manufacturing of fermented wheat germ extracts and products containing said extracts, characterized by determining the formulation A250 of Claim 1 in said extracts and products.

22. Treatment according to Claims 17-20, characterized by administering to the patient an effective amount of the pharmaceutical preparation containing said formulation A250 of Claim 13.