

THE PATENTS ACT, 1970
The Patents Rules, 2003

(SECTION 25(1) and RULE 55)

In the matter of the application for Patent Appln. No. 201641013908

And

In the matter of representation by way of opposition u/s 25(1) to the
grant of patent thereon by

LAILA IMPEX Applicant

CSIR-Traditional Knowledge Digital Library Opponent
Unit, 14, Satsang Vihar Marg, NEW DELHI

Present:

BINA DANDEKAR Agent for Applicant

HEARING HELD BEFORE
Dr. SHARANA GOUDA,
DEPUTY CONTROLLER OF PATENTS & DESIGNS

DECISION

The applicant **LAILA IMPEX** filed a application No. 201641013908 on 21st April, 2016 (which is postdated to 21st May, 2016) for granting of a patent for their invention entitled “DIETARY SUPPLEMENTS AND COMPOSITIONS FOR ENHANCING PHYSICAL PERFORMANCE AND ENERGY LEVELS”. The first examination report was issued on 31st October, 2022. The applicant’s agent replied to the FER vide their letter dated 28th April, 2023. An opposition to the grant of a Patent under section 25(1) was filed by CSIR, New Delhi on 7th October, 2022. The pregrant hearing was held on 12th October, 2023 and only Applicant’s agent attended the hearing. The Applicant’s agent has submitted written submissions post hearing on 25th October, 2023.

The amended claims 1 to 11 submitted on 25th October, 2023 along with written submissions to hearing u/s 25(1) of the Act are as below:

1. A dietary supplement or herbal composition for increasing energy levels, endurance, mental alertness, muscle mass muscle strength, for sarcopenia and muscular atrophy comprising a synergistic mixture of at least two ingredients, wherein the synergistic composition comprises; a first mixture comprising an extract of *Mangifera indica* and a second component in a ratio of from 4:1 to 1:4, said second component being an extract of a plant selected from the group consisting of *Acacia nilotica*, *Cassia auriculata*, *Sphaeranthus indicus*, and mixtures thereof; or a second mixture comprising an extract of *Cassia auriculata* and a fourth component in a ratio of from 4:1 to 1:4, said fourth component being an extract of a plant selected from the group consisting of *Acacia nilotica*, *Punica granatum*, *Rubia cordifolia*, and mixtures thereof; or a mixture thereof.
2. The dietary supplement or herbal composition as claimed in claim 1, comprising an extract of *Bauhinia racemosa*, *Woodfordia fruticosa* or a mixture thereof.
3. The dietary supplement or herbal compositions as claimed in claim 1, wherein the composition contains the extracts of *Mangifera indica* and the second component in a ratio of 2:1 and 1:3, the second component selected from the extracts of *Sphaeranthus indicus*, *Acacia nilotica*, *Cassia auriculata*, or a mixture thereof which further contain optionally an excipient, diluent or carrier.
4. The dietary supplement or herbal compositions as claimed in claim 1, wherein the composition comprises the extracts of *Cassia auriculata* and the fourth component in a ratio of between 3:1 and 1:3, the fourth component selected from the extracts

of *Acacia nilotica*, *Punica granatum*, *Rubia cordifolia*, which further contain optionally an excipient, diluent or carrier.

5. The dietary supplement or herbal composition as claimed in claim 1, wherein the compositions further contain at least optional ingredient selected from non-limiting components such as vitamins selected from B vitamins, including thiamine, riboflavin, niacin, pantothenic acid, pyridoxine, biotin, cyanocobalamin, choline and/or folic acid, including the reduced forms of folic acid such as but not limited to folinic acid, calcium folinate, methyltetrahydrofolate, and particular forms of B vitamins in the composition may include d-Calcium pantothenate, niacinamide, pyridoxine hydrochloride, and thiamine mononitrate; or amino acids.
6. The dietary supplement or herbal composition as claimed in claim 1, wherein the solvent media used for producing the extracts from *Acacia nilotica*, *Bauhinia racemosa*, *Cassia auriculata*, *Mangifera indica*, *Woodfordia fruticosa* *Sphaeranthus indicus*, *Punica granatum* and *Rubia cordifolia* selected from C1-C5 alcohols, like ethanol, methanol, isopropanol, butanol; water and mixtures thereof; C1-C7 hydrocarbons such as hexane; esters like ethyl acetate; MIBK, acetone and the like and mixtures thereof.
7. The dietary supplement or herbal composition as claimed in claim 1, wherein the plant parts for *Acacia nilotica*, *Bauhinia racemosa*, *Cassia auriculata*, *Mangifera indica*, *Woodfordia fruticosa* *Sphaeranthus indicus*, *Punica granatum* and *Rubia cordifolia* for producing the extract is selected from leaves, stems, tender stem, aerial parts, fruit, fruit rind, seed, flower heads, root, bark or whole plant or mixtures thereof.

8. The dietary supplement or herbal composition as claimed in claim 1, wherein the extract or fraction derived from *Acacia nilotica*, *Bauhinia racemosa*, *Cassia auriculata*, *Mangifera indica* and *Woodfordia fruticosa* or their composition are standardized to the selective active phytochemical markers or phytochemicals markers present in the respective extracts or fraction.
9. The dietary supplement or herbal composition as claimed in claim 1, wherein individual extracts can be formulated into a dry powder, liquid form, food product, beverage, dietary supplement or any suitable form such as tablet, a capsule or a soft chewable tablet, soft gel capsule, controlled release tablets, using controlled release polymer-based coatings by the techniques including nanotechnology, microencapsulation, colloidal carrier systems and other drug delivery systems.
10. The dietary supplement or herbal composition as claimed in claim 1, wherein individual extracts can be formulated into the dosage form of healthy foods, or food for specified health uses such as solid food like chocolate or nutritional bars, semisolid food like cream or jam, or gel and also beverage and the like, such as refreshing beverage, lactic acid bacteria beverage, drop, candy, chewing gum, gummy candy, yoghurt, ice cream, pudding, soft adzuki bean jelly, jelly, cookie, tea, soft drink, juice, milk, coffee, cereal, snack bar and the like.
11. The dietary supplement or herbal composition as claimed in claim 1, wherein individual extracts derived from *Acacia nilotica*, *Bauhinia racemosa*, *Cassia auriculata*, *Mangifera indica*, and *Woodfordia fruticosa* or their compositions thereof can further be combined optionally with one or more pharmaceutically or dietetically acceptable excipients, carriers and diluents, which include but not

limited to glucose, fructose, sucrose, maltose, yellow dextrin, white dextrin, aerosil, microcrystalline cellulose, calcium stearate, magnesium stearate, sorbitol, stevioside, corn syrup, lactose, citric acid, tartaric acid, malic acid, succinic acid, lactic acid, L-ascorbic acid, dl-alpha-tocopherol, glycerin, propylene glycol, glycerin fatty ester, poly glycerin fatty ester, sucrose fatty ester, sorbitan fatty ester, propylene glycol fatty ester, acacia, carrageenan, casein, gelatin, pectin, agar, vitamin B group, nicotinamide, calcium pantothenate, amino acids, proteins, calcium salts, pigments, flavors, preservatives, distilled water, saline, aqueous glucose solution, alcohol, propylene glycol and polyethylene glycol, various animal and vegetable oils, white soft paraffin, paraffin, flavorants, colourants and wax.

SUMMARY OF REPLY & ARGUMENTS OF THE APPLICANT

The summary of the arguments of the Applicant's agent are as following:

6. The claimed invention involves inventive step –Section 25(1) (e) is therefore not applicable.

Exhibit 1: Cikkana Khadava)

Exhibit 2: Gauda Madya

Exhibit 3: Dadima Guna

Exhibit 4: Rajamra Guna

Exhibit 5: Nagabala Guna

6.1. The Opponent has alleged in the Pre-grant Opposition draft that the present invention lacks inventive step in view of the above cited prior art documents (Exhibit 1 to Exhibit 5) which the Applicant out rightly rejects for the following reasons: 6..1.1 With reference to the disclosure of Exhibit I (Cikkana Khadava), the Applicant states that the formulation disclosed for Cikkana Khadava comprises Curcuma longa, Mangifera indica Linn, Zingiber officinale Roscose for strength promoting. The Applicant submits that the composition disclosed in Cikkana Khadava is entirely different from the composition claimed in the amended claim 1 of the present invention. Example 8 on page 28 of the as filed complete specification disclose the composition containing extracts of Mangifera indica

(LN16014) and *Sphaeranthus indicus* extract (LN16015) in 1:2 ratio. Table 2 (Nitrite assay) on page 34 of the complete specification depict the enhanced increase in intracellular ATP content summarized in table 5 on page 36 of the complete specification. In light of the same, the Applicant submits that not only the composition of the Exhibit I is different from the present invention as claimed in amended claim 1, but said Exhibit I has failed to disclose the efficacy at the cellular level unlike the present invention. The Applicant therefore states that Exhibit I document should be dismissed out rightly.

6.1.2 With reference to Exhibit 2 (*Gauda Madya*), the said Exhibit 2 disclose the composition comprising *Woodfordia fructosa*, jaggery and water. The Applicant at the instant states that the composition disclosed in Exhibit 2 is irrelevant to the present invention in view of the amended claims. The present invention provides a dietary and herbal composition comprising a first mixture comprising an extract of *Mangifera indica* and a second component in a ratio of from 4:1 to 1:4, said second component being an extract of a plant selected from the group consisting of *Acacia nilotica*, *Cassia auriculata*, *Sphaeranthus indicus*, and mixtures thereof; or a second mixture comprising an extract of *Cassia auriculata* and a fourth component in a ratio of from 4:1 to 1:4, said fourth component being an extract of a plant selected from the group consisting of *Acacia nilotica*, *Punica granatum*, *Rubia cordifolia*, and mixtures thereof; or a mixture thereof; and may further comprise the extract of *Woodfordia fruticosa* for increasing energy levels, endurance, mental alertness, muscle mass muscle strength, for sarcopenia and muscular atrophy which the Exhibit 2 does not remotely teach. In light of the same, the Applicant submits that cited prior art document (Exhibit 2) should be dismissed totally.

6.1.3 The Exhibit 3 related to *Dadima Guna* comprises single compound formulation consisting of useful parts of *Punica granatum* as an appetizer, promoting desire for food. The Applicant out rightly states that Exhibit 3 is an irrelevant document since it does not remotely mention the extracts derived from the plants claimed in the amended claim 1 viz. *Mangifera indica* *Acacia nilotica*, *Cassia auriculata*, *Sphaeranthus indicus*, *Punica granatum*, *Rubia cordifolia*, *Woodfordia fruticosa* or mixtures thereof for increasing energy levels, endurance, mental alertness, muscle mass muscle strength, for sarcopenia and muscular atrophy. Hence, the Applicant submits that the cited document Exhibit 3 should be dismissed in totality.

6.1.4 With reference to Exhibit 4, the *Rajamra Guna* formulation consists of useful parts of a single ingredient i.e. *Mangifera indica* for strength promoting. In the present invention as claimed in claim 1,

the dietary supplement or herbal composition comprises a first mixture comprising an extract of *Mangifera indica* and a second component in a ratio of from 4:1 to 1:4, said second component being an extract of a plant selected from the group consisting of *Acacia nilotica*, *Cassia auriculata*, *Sphaeranthus indicus*, and mixtures thereof for increasing energy levels, endurance, mental alertness, muscle mass muscle strength, for sarcopenia and muscular atrophy. The Applicant reiterate that the teachings of Exhibit 4 are irrelevant to the present invention as claimed in the amended claim 1. Hence, the cited prior art document as Exhibit 4 is liable to be dismissed.

6.1.4 With reference to Exhibit 5 related to Nagabala Guna formulation, said formulation consists of useful parts of *Sida cordata* (Burm.F), *Borsuum* Syn.: *S.veronicaefolia* Lam. for strength promoting, antiageing. It is further stated in said document that "it is similar/like *Bauhinia racemosa* Lam; fruit. The Applicant submits that the formulation disclosed in Exhibit 5 is way different from the present invention as claimed in claim 1. Hence, the Exhibit 5 should be dismissed in toto.

7. From the foregoing analysis, the Applicant submits that the present invention as claimed in the amended claims 1-11 with the enhanced activity such as the increased nitric oxide synthesis in endothelial cells; increase in the ATP content; which activates protein synthesis/mTOR signaling, mitochondrial biogenesis, and myogenesis (myotube formation); and activates MyoD and myogenin signaling in skeletal muscle cells demonstrated in the tables viz. table 2 to table 18 of the complete specification of the impugned patent application is non-obvious and inventive over the disclosures of the prior arts (Exhibit 1 to Exhibit 5) taken alone or in combination. A person skilled in the art cannot arrive at the impugned invention with the enhanced activity at intracellular level from the teachings of Exhibit 1 to Exhibit 5 taken individually or collectively thus rendering the invention claimed in the subject patent application inventive and non-obvious to a person skilled in the art.

8. The Applicant in view of the preceding paragraph submits that that the objection u/s 25(1)(e) ought to be rejected out rightly. The Applicant submits that the amended claims 1-11 annexed herewith as Annexure I (clean copy) of the present invention clearly deserves grant of patent.

FINDINGS OF THE PROCEEDINGS:

Considering the representation by way of Opposition u/s 25(1) of the Patents Act, 1970, the hearing was held with the applicant and applicants arguments along with the written submissions to the hearing during the hearing are considered and the summary of my findings are as following:

Opponent did not attend the hearing and the representation given also not emphasized any of the specific grounds of opposition under section 25 (1) of the Patents Act, 1970 and only stated that as per the Guiding Principles 1, 2, 3 and 6 vide para 14 of the 'Guidelines of CGPDTM for processing of Patent Applications relating to Traditional Knowledge and Biological Material', the referred claims of the patent application cannot be considered as inventive. The Opponent cited prior art documents 1 to 5 as Exhibits 1 to 5.

GROUND: LACK OF INVENTIVE STEP

The Opponent's representation is that the alleged invention claimed in the application is obvious to a person skilled in the art by the cited prior art documents from TKDL database as Exhibits 1 to 5.

On perusal of the disclosures and teachings in cited documents Exhibit 1 to 5 along with the submissions by the opponent in representation and also considering the arguments during the hearing by the Applicant's agent, it is clear that none of the cited documents Exhibit 1 to 5 to either alone or in combination with each other make the invention dietary supplement or herbal composition for increasing energy levels, endurance, mental alertness, muscle mass muscle strength, for sarcopenia and muscular atrophy claimed in amended claims 1 to 11 of the instant application obvious to a person skilled in the art as the cited prior art documents

teachings are not disclosing the ratio of 4:1 to 4:1 for first and second mixture as claimed in amended claim 1. I am in agreement with the Applicant's agent that these cited documents, Exhibits 1 to 5 disclosures do not have specific features of the claimed composition in amended claim 1-11 to make the claimed composition obvious to a person skilled in the art and hence the claims 1 to 11 involve inventive step vis-à-vis the cited documents, Exhibits 1 to 5. In my opinion, the disclosures in these documents do not anticipate the composition claimed or do not make the composition claimed in the instant invention amended claims 1 to 11 obvious vis-à-vis the cited documents, Exhibits 1 to 5 and hence meets the criteria of the patentability as per the provisions of the section 2 (1) (ja) of the Patents Act, 1970 as per the Guiding Principles 1, 2, 3 and 6 vide para 14 of the 'Guidelines of CGPDTM for processing of Patent Applications relating to Traditional Knowledge and Biological Material'. Therefore, the opponent failed to establish this ground of opposition of the Patents Act, 1970.

In view of my findings as above for the opposition ground of inventive step, the amended composition claims 1 to 11 of the instant patent application do meet the requirements of the Patents Act, 1970, hence I herewith order for grant of a patent.

Dated this 12th day of December, 2023