Annexure-2

GUIDELINES FOR PROCESSING PATENT APPLICATIONS OF AYUSH SYSTEMS AND RELATED INVENTIONS

COVER PAGE

Photograph of medicinal plant (like *Ashwagandha*, *Guduchi* etc.) having Geo-tagging granted by IP office along with specific designed logo, will placed on the cover page.

I. Introduction

Ayush systems of healthcare include Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy. Ministry of Ayush has mandate to develop Ayush systems. These guidelines are intended to provide clarity to the filing and processing patent applications of Ayush systems and related inventions. In this context, it may be noted that in the year 2012, Indian Patent office has also issued guidelines on **"GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL."**

India has played a pivotal role in the decade old efforts of developing countries on the global platform for bringing the protection of traditional knowledge at the center stage of the International Intellectual Property System. These efforts have resulted *inter alia* in setting up of an Inter-Governmental Committee (IGC) on Intellectual Property, Traditional Knowledge, Genetic Resources and Folklore by WIPO and the Doha Ministerial Declaration of the year 2001 wherein it was decided to establish a relationship between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) on the issue of Access to Genetic Resources and the fair and equitable sharing of the benefits arising from their utilization. In view of these global initiatives, it is envisaged to establish a robust system of Intellectual Property related to Ayush systems of healthcare in the country. Thus, "**GUIDELINES FOR PROCESSING PATENT APPLICATIONS OF AYUSH SYSTEMS AND RELATED INVENTIONS"** are framed to dissipate comprehensive information on patent filing and processing. The present guidelines do not replace the existing "Guidelines for processing of patent applications relating to Traditional Knowledge and Biological Material", rather these guidelines are intended to complement them and are focused on Ayush systems of healthcare for better understanding of Ayush stakeholders.

II. Ayush systems of healthcare –

Ayush system of medicine includes Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy. Government of India has a dedicated Ministry of Ayush for reviving the profound knowledge of our Ayush systems and ensuring the optimal development and propagation of the Ayush systems of healthcare. Ministry of Ayush has taken various initiatives for the promotion and propagation of Ayush products, research and education in Ayush system within the country and across the globe.

Area of Scope for Ayush related inventions –

- Ayush product(s) and Equipment(s) / Device(s) used in Ayush systems
- Food recipes/ Nutraceuticals described in Ayush systems

Product and processes in the aforementioned areas deserve IPR protection subject to qualifying the criteria of patentability under Section 2 (1) (j) and Section 3 of the Patents Act, 1970.

III. Existing Provisions and Procedure for Protection of Traditional Knowledge (TK), Ayush systems and related inventions

Indian law has adequate provisions for the protection of TK. By its very definition, TK is in the public domain and hence, any application for patent relating to TK does not qualify as an invention under section 2 (1) (j) of the Patents Act, 1970, which defines that "*invention means a new product or process involving an inventive step and capable of industrial application"*. Further, under section 3(e) of the Patents Act "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable. The Indian Patents Act also has a provision under Section 3 (p), wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components" is not an invention and hence, not patentable, within the meaning of the Patents Act. Additionally, sections 3 (b), (c), (d), (f), (h), (i) and (j) are of relevance with respect to the patent applications based on Ayush systems and related inventions.

The following sections of the Patents Act, 1970 are emphasized in the context of examination of applications based on Ayush systems and related inventions:

S.no.	Sections of the Patents Act, 1970	Details
1.	**Section 2**	I. Section 2 (1) (ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry; II. Section 2 (1) (j) "invention" means a new product or process involving an inventive step and capable of industrial application; III. Section 2 (1) (ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes

		the invention not obvious to a person skilled in the art IV. Section 2 (1) (l)"new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e.,the subject matter has not fallen in public domain or that it does not form part of the state of the art;
2.	**Section 3 (Inventions not patentable)**	I. Section 3 (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws; II. Section 3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment; III. Section 3 (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature; IV. Section 3 (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy; V. Section 3 (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; VI. Section 3 (h) a method of agriculture or horticulture; VII. Section 3 (i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render

		them free of disease or to increase their economic value or that of their products. VIII. Section 3 (j) plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals; IX. Section 3 (k) a mathematical or business method or a computer programme per se or algorithms; X. Section 3 (p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Applications related to Ayush systems and related inventions are critically examined with respect to requirements of full and particular disclosure of the invention, its operation or use and the method by which it is to be performed along with the best method of performing the invention by way of working examples known to the applicant in the complete specification as provided under Section 10 (4) (a) & (b) and Section 10 (5) of the Patents Act, as below:

S.no.	Sections of the Patents Act, 1970	Details
1.	**Section 10 (4)**	Every complete specification shall— (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and (c) end with a claim or claims defining the scope of the invention for which protection is claimed; (d) be accompanied by an abstract to provide technical information on the invention: Provided that— (i) the Controller may amend the abstract for providing better information to third parties; and (ii) if the applicant mentions a biological material in the specification

		which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— (A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period; (B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution; (C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority; (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.
2.	**Section 10 (5)**	The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.

Note: I, the source and geographical origin of the biological material used in the invention shall be disclosed in the specification in accordance with section 10 (4) (D) of the Patents Act.

Permission from National Biodiversity Authority (NBA):

a) In Form-1 of the Patent Rules, 2003, the applicant is required to furnish a declaration *"the invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us"*. However, it is observed that the wording of this declaration is not in line with the mandate of the BD Act. The BD Act states that NBA approval/registration (based on the class of the applicant) is required only when the invention is BASED on research or information on biological resources accessed from India. Applicant for patent is not required to obtain NBA approval merely for using the biological resources from India in his work. For eg. If the invention

is for a modified device for dispensation of an ayurvedic medicine, then the NBA permission would not be ideally required for merely by the mention of ayurvedic medicine which can be dispensed using the device in the Patent specification. Applicant shall be required to give the declaration only when the invention is based on research on biological resources obtained from India. For e.g., Invention is an extract of certain specific plants obtained from India which could be useful for the treatment of a disease.

b) **Implications for Non- disclosure or wrong mention of the source or geographical origin of biological material** under the Patents Act, 1970-

Applications for patents based on TK and/or biological material can be refused under section 15 if not complying with the provisions of the Patents Act or as an outcome of pre-grant opposition under Section 25 (1) and granted patents can be revoked in post-grantopposition under Section 25 (2) of the Patents Act, 1970. Granted patents may be revoked under Section 64 (1) as well.

Non- disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre- and post- grant oppositions as well as a ground for revocation under Sections 25 (1) 25 (2) and 64 (1) respectively of the Patents Act, 1970.

IV The recent Amendments notified as the Biodiversity Amendment Act, 2023 is coming into force from 1 April 2024.

Provisions of Biodiversity Act, 2002 as amended by the Biological Diversity (Amendment) Act, 2023 in relation to use of biological resources in inventions:

S.no.	Sections of the Biodiversity Act, 2002 as amended by the Biological Diversity (Amendment) Act, 2023	Details
1.	**Section 2 (c)**	'(c) "biological resources" include plants, animals, micro-organisms or parts of their genetic material and derivatives (excluding value added products), with actual or potential use or value for humanity, but does not include human genetic material;';
2.	**Section 2 (p)**	"value added products" means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.

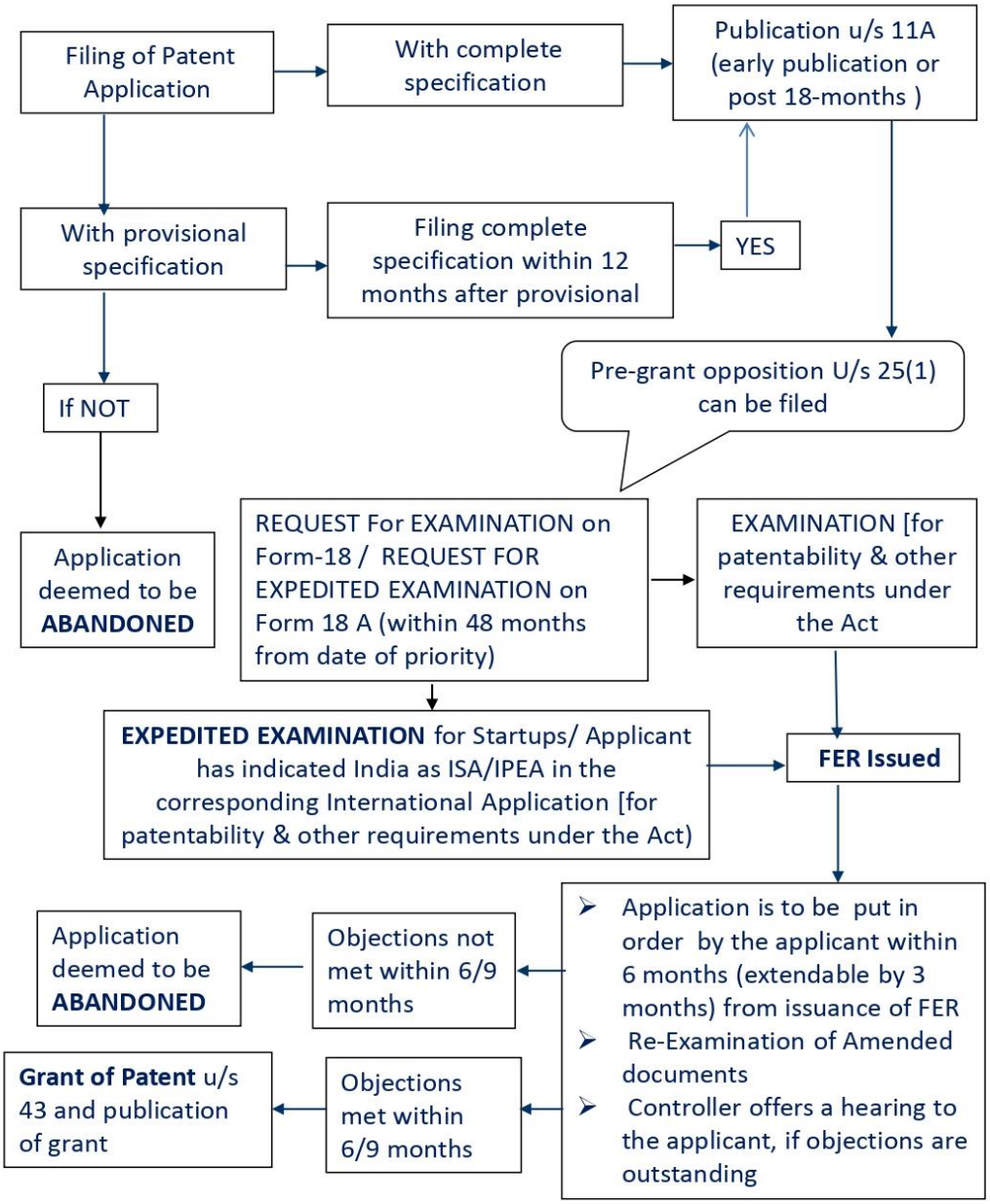
3.	**Section 6 (1)**	Any person or entity covered under sub-section (2) of section 3 applying for an intellectual property right, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto, shall obtain prior approval of the National Biodiversity Authority before grant of such intellectual property rights. (1A) Any person covered under section 7 applying for any intellectual property right, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto, shall register with the National Biodiversity Authority before grant of such intellectual property rights. (1B) Any person covered under section 7 who has obtained intellectual property right, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto, shall obtain prior approval of the National Biodiversity Authority at the time of commercialization.

The Biological Diversity (Amendment) Act, 2023 has a penal provision in this regard under section 55 (1) which provides that *"If any person or entity covered under sub-section (2) of section 3 or section 7 contravenes or attempts to contravene or abets the contravention of the provisions of section 3 or section 4 or section 6 or section 7, such person shall be liable to pay penalty which shall not be less*

than one lakh rupees, but which may extend to fifty lakh rupees, but where the damage caused exceeds the amount of penalty, such penalty shall be commensurate with the damage caused, and in case, the failure or contravention continues, an additional penalty may be imposed, which shall not exceed one crore rupees and such penalty shall be decided by the adjudicating officer appointed under section 55A".

IV. Guidelines for processing of patent application:

Overview of patent application procedure (*source: www.ipindia.gov.in)*



a. Filing of patent application –

- An application for a patent for an invention may be made by any of the following persons either alone or jointly with any other person:
  - True and first inventor
  - True and first inventor's assignee
  - Legal representative of any deceased true and first inventor or his/her assignee
- A patent application can be submitted through online or physical mode at four locations of Indian Patent Office viz. Kolkata, Delhi, Chennai and Mumbai.
- For more details, "Manual of Patent Office Practice And Procedure" may be referred **(**available at https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure.pdf)

b. Screening and classification -

All patent applications relating to Ayush systems and related inventions are screened as "Traditional Knowledge" by dedicated team at Indian Patent Office. The team accords appropriate IPC classification for such TK applications so that these applications can be properly routed for examination to the respective groups such as Chemistry, Pharmaceuticals, Agrochemicals, Biotechnology, Microbiology, Biochemistry, Food, Mechanical, etc. e.g., C07D, C07G5/00 (for Chemical), A61K, A61L (for Pharmaceuticals), A01N (for Agrochemcials), C12S, C12N, C07K4/00; 14/00 (for Biotechnology), C12N, C12P, C12Q (for Microbiology), C12F, C12G (for Biochemistry), A23C, A23L (for Food), B25F (for Mechanical), etc.

c. Examination:

The patentability criteria for examination of Patent application are Novelty and Inventive step (non-obviousness) and industrial application. In every case related to TK and/or biological material, the Examiner of patent application shall carry out a thorough search for anticipation in TK and/or other databases. If any citation is made from TK database in the Examination Report, then copy of the citation (English translated) may be asked by the applicant from the patent office as mentioned in Examination Report. List of some databases to be referred for Ayush systems and traditional knowledge are given at **Annexure-II.**

d. Guiding principles for assessment of patent applications:

While considering the Ayush based inventions, the following guiding principles must be followed –

Guiding Principle 1:	**If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known in Ayush systems. However, processes for obtaining above mentioned extracts/isolates may be considered patentable subject to the requirements of novelty and inventive step.**

When the subject-matter of claims relates to product claims referring to extracts of plant materials containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or specific plant part is pre-known in Ayush systems.

However, if the claims relate to product claims referring to alkaloids and/or active principles obtained from the plants or specific plant part and structures of the said alkaloids and/or active principles are characterized, which do not form the part of the prior art, such claims cannot be said to involve an inventive step, since the use of said plant materials and their therapeutic effects are known in Ayush systems.

Thus, it is considered that the prior art motivates the person skilled in the art to isolate the individual ingredients such as alkaloids, flavonoids, phyto-steroids, etc.

Illustration 1: Patent application claims relate to an aqueous extract of *Withania somnifera* plant for the management of stress.

Prior art (TK): Discloses use of Ashwagandha (*Withania somnifera)* for the treatment of stress related disorders in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to an extract of *Withania Sominfera* plant. Based on the prior art, it can be objected that the aqueous extract of *Withania somnifera* would be useful in treatment of chronic stress disorders such as insomnia, gastric ulcers, hyperacidity, restlessness and depression. Therefore, the subject-matter of claims is not considered as novel over the description in Ayush systems.

Illustration 2: Patent application claims relate to an alkaloid, Chamaemeloside, derived from Roman or German chamomile for the treatment of Cancer, Diabetes mellitus, Arthritis, Acne vulgaris, Eczema and for wound healing.

Prior art (TK): Discloses use of German chamomile (from which Chamaemeloside is derived) in wound healing and for the treatment of cancer, diabetes mellitus, arthritis, acne vulgaris and eczema in Ayurveda and Unani systems of medicine. The prior art does not disclose the Chamaemeloside.

Analysis: The claims of alleged invention relate to Chamaemeloside derived from Roman or German chamomile. Based on the prior art, it can be objected that German or Roman chamomile (from which Chamaemeloside is derived) has already been used alone or in combination with other ingredients for afore-mentioned indications and therefore, the prior art motivates the person skilled in the art to isolate and identify the active ingredient such as Chamaemeloside, which has the same therapeutic effects. Hence, the product arrived at by isolation and characterization cannot be considered to involve an inventive step in the light of prior art .However, the process of isolation (which is not claimed in this illustration) could have been considered as inventive and patentable, subject to the patentability criteria. The fact that a product claim is not patentable due to existence of prior art does not necessarily mean that a process for isolation of the product is not patentable. Such processes could be patentable if they satisfy the provisions of the Patents Act.

Illustration 3: Process for the extraction of berberine from leaves of *Coscinium fenestratum*, wherein an improved yield of berberine is obtained.

Prior art (TK): The process of isolation of berberine from stem is disclosed in the prior art.

Analysis: In the process as disclosed in this invention, the yield of berberine per gram of leaves and the purity of berberine obtained is significantly higher as compared to the prior art. Further, the present invention uses low temperature and minimum chemicals to obtain high purity berberine, which is not disclosed in the prior art. So, inventive merits can be acknowledged and the process is patentable.

Guiding Principle 2:	**In case combination of ingredients from plants/minerals/animal origin/ existing formulations already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further ingredients from plants/minerals/animal origin/ existing formulations with the same known therapeutic effect would be more effective than each of the ingredient when applied separately (additive effect). However, specific ratios leading to unexpected technical effect of such combinations may be considered to establish non-obviousness.**

Illustration 1: Patent application claims relate to a composition comprising of *Calendula officinalis*, *Aloe vera* and *Centella asiatica* as healing agent and for treatment of wound.

Prior art (TK): Discloses independent use of *Calendula officinalis*, *Aloe vera* and *Centella asiatica* for the treatment of wound and as a Cicatrizant/ healing agent in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention were on a composition. Based on the prior art, it can be objected that the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination. It would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect). However, if such combination demonstrates unexpected synergistic effect, it may be considered to establish non-obviousness.

Illustration 2: Patent application Claims relate to synergistic anti-acne topical composition comprising of extracts of *Symplocos racemosa*- 0.5 gm, *Salmalia malabarica*- 0.5gm, *Picrorhiza kurroa*-0.5gm, *Vitex negundo* -0.5gm, *Embelia ribes*-3gm, *Terminalia chebula*- 3gm, and *Terminalia bellerica*-2gm.

Prior art (TK): Discloses formulations comprising one or more of the ingredients selected from *Symplocos racemosa, Salmalia malabarica, Picrorhiza kurroa, Vitex negundo, Embelia ribes, Terminalia chebula,* and *Terminalia bellerica* for different uses including skin disorders.

Analysis: The cited prior art, though disclosing the different ingredients recited in the claims for the treatment of same indication, do not disclose the exact combination of the ingredients in the claimed ratio. In view of the synergistic data provided in specification, the inventive step has been convincingly established and distinguishing the invention from the prior art.

Note- Synergism is the interaction of two or more substances to produce a combined effect greater than the sum of their individual effects. Experimental results should prove that the combined action of all the given ingredients is greater than the sum of their individual effects. A brief about synergism along with illustrations on synergistic data is given at **Annexure III.**

Guiding Principle 3:	**In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease. However, unexpected technical effect of such combinations may be considered to establish non-obviousness.**

Illustration 1: Patent application claims relate to a combination of two constituents of water extract of *Cucumis melo*, along with *Citrus aurantifolia*, for the treatment of vitiligo.

Prior art (TK): Discloses usefulness of only one of the constituents, watery extract of *Cucumis melo* for its anti-vitiligo property in the Unani system of medicine.

Analysis: The claim of alleged invention relates to a composition comprising two constituents and not on

a single constituent, the watery extract *Cucumis melo* for its anti-vitiligo property. Based on said cited documents, it can be objected that if one ingredient here, *Cucumis melo*, was already known for the treatment of vitiligo, then it is necessarily expected that a combination comprising this known active ingredient must be effective for treating vitiligo. As long as no surprising (superior) effect of the claimed combination vis-a-vis the already known product comprising *Cucumis melo*, inventive step cannot be acknowledged.

Illustration 2: Patent application claims relate to a combination of three constituents containing Maghz-e-Karanjwa (*Caesalpinia bonduc* (Tinn.), Gaozaban (*Onsoma bracteatum* Wall.) and Kasni (*Cinchorium intybus*) as one of the constituent, for the treatment of worm infestation and anemia.

Prior art (TK): Maghz-e-Karanjwa (*Caesalpinia bonduc* (Tinn.) is already known for the treatment for worm infestation only.

Analysis: The combination of three constituents has shown unexpected and synergistic effect in the treatment of worm infestation and anemia. In view of the data provided in respect of unexpected and synergistic effect, the inventive step may be considered for distinguishing invention from the traditional knowledge.

Guiding Principle 4:	**Discovering the optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.**

In case of inventions relating to selection of optimum or workable range of ingredients, this is to be borne in mind that the selection of a particular range of known ingredients is not inventive since the selection of optimum or workable range is well within the expectation of a person skilled in the art.

Illustration 1: Patent application claims relate to a formulation comprising at least two of the following: an extract of *Pongamia pinnata* (in the range of 2 to 20%), an extract of *Lawsonia alba* (in the range of 5 to 15%), an extract of *Dhatura alba* (in the range of 2 to 20%) and an extract of *Cocos nucifera* (in the range of 20 to 60%) for the management of chronic ulcer, diabetes ulcer, and the management of bleeding in cuts and wounds.

Prior art (TK): Discloses use of said plants for the treatment of ulcer/wound in Ayurveda, Unani and Siddha systems of medicine.

Analysis: The claims of alleged invention relate to a composition comprising plant parts in a specified ratio. The claims can be objected as not patentable in so far as the alleged invention is obvious over *Agasthiyar* (TK) which taught a composition of extracts of two of the claimed plants, *Karanj* and *Heena*

formulated as oil for topical treatment of ulcers and wounds. Although, cited art does not specifically teach adding the ingredients in the percentages claimed by the applicant, the amount of specific ingredient in a composition is clearly a result affecting variable, which a person skilled in the art would routinely optimize.

Guiding Principle 5:	**In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking one component out of them cannot be considered as inventive.**

Illustration 1: Patent application claims relate to an extract of *Zingiber zerumbet* (bitter ginger) for inflammation and also for allergic disorder like Asthma.

Prior art (TK): Discloses use of *Zingiber zerumbet* (bitter ginger) along with few other ingredients for the treatment of inflammation and Asthma in Unani system of medicine.

Analysis: The claims of alleged invention relate to an extract of *Zingiber zerumbet*. As per the prior art disclosure, the multi-component formulation comprising *Zingiber zerumbet* have the same therapeutic activity (i.e. anti-bronchial asthmatic), therefore it is not surprising that one single component namely *Zingiber zerumbet* taken out of them again would have the same therapeutic activity. Hence, a person skilled in the art would have been motivated to arrive at the invention without exercise of inventive skills and thus, the claims of alleged invention can be objected for lacking in inventive step.

Guiding Principle 6:	**If the subject matter of the claims relates to inventions regarding equipment / device used in Ayush systems, then such inventions may be patentable if novel and inventive over the prior art.**

Illustration 1: Advanced automated system or device for Therapeutic Emesis *(Vamana Karma)* comprising a frame holding primary and secondary sinks connected with sensing elements for pH, temperature, weight, volume & a display unit along with vomitus collecting bag and its method for fabrication.

Prior art (Ayurveda): Procedure for performing *Vamana Karma* is disclosed in Ayurveda but it does not disclose any device along with sensors, for doing such procedure.

Analysis: The claims relate to advanced automated system or device for Therapeutic Emesis *(Vamana Karma)* and its method for fabrication. As per the prior art (Ayurveda), the procedure for performing *Vamana Karma* is well documented however, an automated device for conducting *Vaman Karma*,

comprising pH, temperature, and volume sensors for analyzing the vomitus and hygienically conducting the said *karma* was not known and can be considered patentable.

******

Annexure –I

Form-1 of the Patent Rules, 2003

"**FORM 1** THE PATENTS ACT 1970 (39 of 1970) and THE PATENTS RULES, 2003 **APPLICATION FOR GRANT OF PATENT** (See section 7, 54 and 135 and sub-rule (1) of rule 20)			(FOR OFFICE USE ONLY)		
			Application No.		
			Filing date:		
			Amount of Fee paid:		
			CBR No:		
			Signature:		
1. APPLICANT'S REFERENCE / IDENTIFICATION NO. (AS ALLOTTED BY OFFICE)					
2. TYPE OF APPLICATION [Please tick (✓) at the appropriate category]					
Ordinary ( )		Convention ( )		PCT-NP ( )	
Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )
3A. APPLICANT(S)					
Name in Full		Nationality	Country of Residence	Address of the Applicant	
				House No.	
				Street	
				City	
				State	
				Country	
				Pin code	
3B. CATEGORY OF APPLICANT [Please tick (✓) at the appropriate category]					
Natural Person ( )	Other than Natural Person				
	Small Entity ( )		Startup ( )	Others ( )	
4. INVENTOR(S) [Please tick (✓) at the appropriate category]					
Are all the inventor(s) same as the applicant(s) named above?	Yes ( )		No ( )		
If "No", furnish the details of the inventor(s)					
Name in Full	Nationality	Country of Residence	Address of the Inventor		
			House No.		
			Street		
			City		
			State		
			Country		
			Pin code		

5. TITLE OF THE INVENTION		
6. AUTHORISED REGISTERED PATENT AGENT(S)	IN/PA No.	
	Name	
	Mobile No.	
7. ADDRESS FOR SERVICE OF APPLICANT IN INDIA	Name	
	Postal Address	
	Telephone No.	
	Mobile No.	
	Fax No.	
	E-mail ID	

8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION

Country	Application Number	Filing date	Name of the applicant	Title of the invention	IPC (as classified in the convention country)

9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)

International application number	International filing date

10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION

Original (first) application No.	Date of filing of original (first) application

11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main application/patent No.	Date of filing of main application

12. DECLARATIONS

(i) Declaration by the inventor(s)

(**In case the applicant is an assignee**: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

I/We, the above named inventor(s) is/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date
(b) Signature(s)
(c) Name(s)

(ii) Declaration by the applicant(s) in the convention country

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date
(b) Signature(s)
(c) Name(s) of the signatory

(iii) Declaration by the applicant(s)

I/We the applicant(s) hereby declare(s) that: -

- ☐ I am/ We are in possession of the above-mentioned invention.
- ☐ The provisional/complete specification relating to the invention is filed with this application.
- ☐ The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.
- ☐ There is no lawful ground of objection(s) to the grant of the Patent to me/us.
- ☐ I am/we are the true & first inventor(s).
- ☐ I am/we are the assignee or legal representative of true & first inventor(s).
- ☐ The application or each of the applications, particulars of which are given in Paragraph-8, was the first application in convention country/countries in respect of my/our invention(s).
- ☐ I/We claim the priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/us or by any person from which I/We derive the title.
- ☐ My/our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Paragraph-9.
- ☐ The application is divided out of my /our application particulars of which is given in Paragraph-10 and pray that this application may be treated as deemed to have been filed on DD/MM/YYYY under section 16 of the Act.
- ☐ The said invention is an improvement in or modification of the invention particulars of which are given in Paragraph-11.

13. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION

(a) Form 2

Item	Details	Fee	Remarks
Complete/ provisional specification)#	No. of pages		
No. of Claim(s)	No. of claims and No. of pages		
Abstract	No. of pages		
No. of Drawing(s)	No. of drawings and No. of pages		

In case of a complete specification, if the applicant desires to adopt the drawings filed with his provisional specification as the drawings or part of the drawings for the complete specification under rule 13(4), the number of such pages filed with the provisional specification are required to be mentioned here.

(b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(c) Sequence listing in electronic form

(d) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(e) Priority document(s) or a request to retrieve the priority document(s) from DAS (Digital Access Service) if the applicant had already requested the office of first filing to make the priority document(s) available to DAS.

(f) Translation of priority document/Specification/International Search Report/International Preliminary Report on Patentability.

(g) Statement and Undertaking on Form 3

(h) Declaration of Inventorship on Form 5

(i) Power of Authority

(j)……..

Total fee □…….in Cash/ Banker's Cheque /Bank Draft bearing No..... Date……...on ……. Bank.

I/We hereby declare that to the best of my/our knowledge, information and belief the fact and matters slated herein are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this……day of……20……

Signature:

Name:

To,

The Controller of Patents

The Patent Office, at……..

Note: -

* Repeat boxes in case of more than one entry.
* To be signed by the applicant(s) or by authorized registered patent agent otherwise where mentioned.
* Tick (✓)/cross (x) whichever is applicable/not applicable in declaration in paragraph-12.
* Name of the inventor and applicant should be given in full, family name in the beginning.
* Strike out the portion which is/are not applicable.
* For fee: See First Schedule";

Annexure-II

List of some databases to be referred for Ayush systems and traditional knowledge –

1. Ayush Research Portal (https://ayushportal.nic.in)
2. Database of Ayurvedic, Unani, Siddha and Sowarigpa Formulations (https://www.tkdl.res.in)
3. Foundation for Revitalisation of Local Health Traditions (FRLHT) Indian Medicinal Plant Database (https://www.medicinalplants.in)
4. e-Charak portal has been jointly developed by the National Medicinal Plants Board (NMPB), Ministry of Ayush, Government of India and Centre for Development of Advanced Computing (C-DAC) (https://echarak.in/echarak/main.do). It is an e-Channel for Herbs, Aromatic, Raw material and Knowledge and a platform to enable information exchange between various stakeholders involved in the medicinal plants sector.
5. Tribal Digital Document Repository by Ministry of Tribal Affairs, Govt. of India. (https://repository.tribal.gov.in)
6. The Biological Diversity (Amendment) Act, 2023, https://egazette.gov.in/WriteReadData/2023/247815.pdf
7. The Patent Act, 1970. https://ipindia.gov.in/writereaddata/Portal/ev/sections-index.html
8. The Patent Rules, 2003. https://ipindia.gov.in/writereaddata/Portal/ev/rules-index.html

Annexure-III

Brief about synergism along with illustrations on synergistic data

Section 3(e) precludes patenting of "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance". In order to assess whether the invention falls under Section 3(e), it is examined whether there is synergistic effect of claimed composition which is more than the combined effect of each component of the composition when used individually.

Synergism is the interaction of two or more substances to produce a combined effect greater than the sum of their individual effects. The Guidelines for examination of patent applications in the field of Pharmaceuticals provides insight that "if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features" and does not fall within the ambit of mere aggregation of features. Some illustrations demonstrating the assessment of presence of synergism are as follows:

Illustration 1: Patent application claims relate to a composition comprising tamarind seed polysaccharide (TSP) in combination with an extract of *Helichrysum italicum*. The treatment with TSP according to the said patent application is effective in stimulating the antimicrobial response, especially when administered topically to the skin and to the mucosa.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely tamarind seed polysaccharide and extract of Helichrysum italicum. The complete specification contained the following experimental data regarding the expression of beta defensin by normal human epidermal keratinocyte. Beta defensin are host defense peptides having the ability to kill a broad range of microorganisms including bacteria, yeast and viruses.

Products	**Concentration**	**DEFB2 expression (pg/ml)**
Negative ref. (control)	-	0
Positive ref. (LPS)	5 mcg/ml	12
Tamarind Seed Polysaccharide (TSP)	0.2%	40*
Helichrysum italicum extract (HIE)	0.2%	21
HIE + TSP	0.2% + 0.2%	140*

*p < 0.001 vs. control

It is apparent from the table that the combined effect of Helichrysum italicum extract and Tamarind Seed Polysaccharide (140 pg/ml) is higher than the sum of their individual effects (40 pg/ml + 21 pg/ml), thereby indicating synergism between them.

Illustration 2: Patent application claims relate to a composition comprising Vaccinium myrtillus extract and Echinacea sp.extract.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely Vaccinium myrtillus extract and Echinacea sp.extract. The complete specification contained the following experimental data regarding the re-epithelialisation of ulcers by the use of Vaccinium myrtillus extract and Echinacea sp.extract, when used individually and in combination.

Treatment	**Re-epithelialisation**		
	7 days	14 days	28 days
Placebo	0.02 +/- 0.01	0.01 +/- 0.01	0.03 +/- 0.02
Vaccinium myrtillus 0.3%	0.10 +/- 0.03	0.23 +/- 0.13*	0.50 +/- 0.23*
*Echinacea sp.*extract 0.3%	0.01 +/- 0.01	0.20 +/- 0.02*	0.35 +/- 0.02*
Vaccinium myrtillus 0.3% + *Echinacea sp.*extract 0.3%	2.14 +/- 0.73**	4.9 +/- 1.01**	8.30 +/- 1.10**

*P<0.05; **P<0.001 Student's "t" test

The provided data clearly demonstrates that the re-epithelialisation achieved using the composition comprising Vaccinium myrtillus and Echinacea sp. extract is much higher than the sum of re-epithelialisation achieved when these two ingredients are used individually, indicating a synergistic effect between them

Illustration 3: Patent application claims relate to a composition comprising extract of *Andrographis paniculata* and *Ginkgo biloba* extract for the treatment of neurodegenerative disorders.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely extract of *Andrographis paniculata* and *Ginkgo biloba* extract. The complete specification contains the following experimental data regarding the comparative effect of the

claimed composition and its components when used individually, on Experimental Autoimmune Encephalomyelitis (EAE) in 20 transgenic mice. Clinical signs of the disease are recorded daily on the basis of the following scores:

0 : no signs of EAE

1: limp tail

2: weakness of hind legs or abnormal gait

3: complete paralysis of hind legs

4: complete paralysis of hind and fore legs

5: death

The mean clinical data are calculated by adding the daily scores of the mice belonging to the same treatment group and dividing by the number of mice.

Group	**Incidence**	**Score (Maximum)**	**Average Of Maximum Scores**
CONTROL	20/20 (100%)	5	3.9 +/- 0.1
Andrographis paniculata extract	7/20 (35%)	4	2.9 +/- 0.1*
Ginkgo biloba extract	4/20 (20%)	5	3.3 +/- 0.1
Andrographis paniculata extract + *Ginkgo biloba* extract	12/20 (60%)	**2**	**2.2 +/- 0.1****

* $p<0.05$ Student's t-test

** $p<0.01$ vs. control

Based on the data provided in the above given table, the combination of *Andrographis paniculata* extract and *Ginkgo biloba* extract exhibits no incidence of death and much lower maximum scores indicating less severe clinical signs of disease compared to the scores achieved using *Andrographis paniculata* extract and *Ginkgo biloba* extract when used individually, thereby indicating the presence of synergism between the two components.

Illustration IV: Patent application claims relate to a herbal anthelmintic formulation comprising dried extract powder of *Trichosanthes dioica* seeds, dried extract powder of *Prunus persica* leaves, carbopol, microcrystalline cellulose, dibasic calcium phosphate, polyethylene glycol – 400 and sodium benzoate.

Analysis: The claims of alleged invention relate to a formulation of two active ingredients, namely dried extract powder of *Trichosanthes dioica* seeds and dried extract powder of *Prunus persica* leaves. The complete specification provides the following exemplary formulations:

Ingredients	(Weight Per Tablet -500 mg) Ingredients Quantity		
	F1 (1:1)	F2 (3:1)	F3 (1:3)
Trichosanthes dioica seeds dried extract powder	200 mg	300 mg	100 mg
Prunus persica leaves dried extract powder	200 mg	100 mg	300 mg
Carbopol (Sigma-Aldrich)	20 mg	20 mg	20 mg
Microcrystalline cellulose	40 mg	40 mg	40 mg
Dibasic calcium phosphate	30 mg	30 mg	30 mg
PEG- 400	7.5 mg	7.5 mg	7.5 mg
Sodium benzoate	2.5 mg (0.5%)	2.5 mg (0.5%)	2.5 mg (0.5%)

The following experimental data was provided in the complete specification regarding the anthelmintic activity of the claimed formulation and its components when used individually, on round worms, *Ascaridia galli.*

S.No	**Treatment**	**Dose**	**Mean paralysis time (min) ± SEM**	**Mean lethal time (min) ± SEM**
1	(Positive control) Piperazine citrate 500 mg Tablet	20mg/ml	19.14 ± 0.20	25.00± 0.26
2	(Negative Control) 25 ml 2 % DMSO in PBS	25ml	No Paralysis	No death

3	*Trichosanthes dioica seeds dried aqueous extract 500mg*	20mg/ml	32.06 ± 0.41	45.14 ± 0.20
4	*Prunus persica* leaves dried aqueous extract 500mg	20mg/ml	31.18 ± 0.23	42.11 ± 0.13
5	Formulation (F1) Tablet (200mg + 200mg)	20mg/ml	17.40 ±0.25*	22.58± 0.17*
6	Formulation (F2) Tablet (300mg+100mg)	20mg/ml	25.16 ± 0.12	31.00 ± 0.30
7	Formulation (F3) Tablet (100mg+300mg)	20mg/ml	29.26 ± 0.22	33.11 ± 0.27

Based on the data provided in the above given table, the formulations F1, F2 and F3 containing dried extract powder of *Trichosanthes dioica* seeds and dried extract powder of *Prunus persica* leaves exhibited anthelmintic activity. All worms were paralyzed and eventually killed by the all test formulations. F1 formulation (200mg+200mg) i.e. 1:1 ratio of both plants extracts, exhibited maximum efficacy by taking shortest paralysis and lethal times as shown in above given table. The mean paralysis time and mean lethal time exhibited by F1, F2 and F3 was lower than that exhibited by either *Trichosanthes dioica* seeds dried aqueous extract or *Prunus persica* leaves dried aqueous extract, thereby indicating the presence of synergism between the two components.