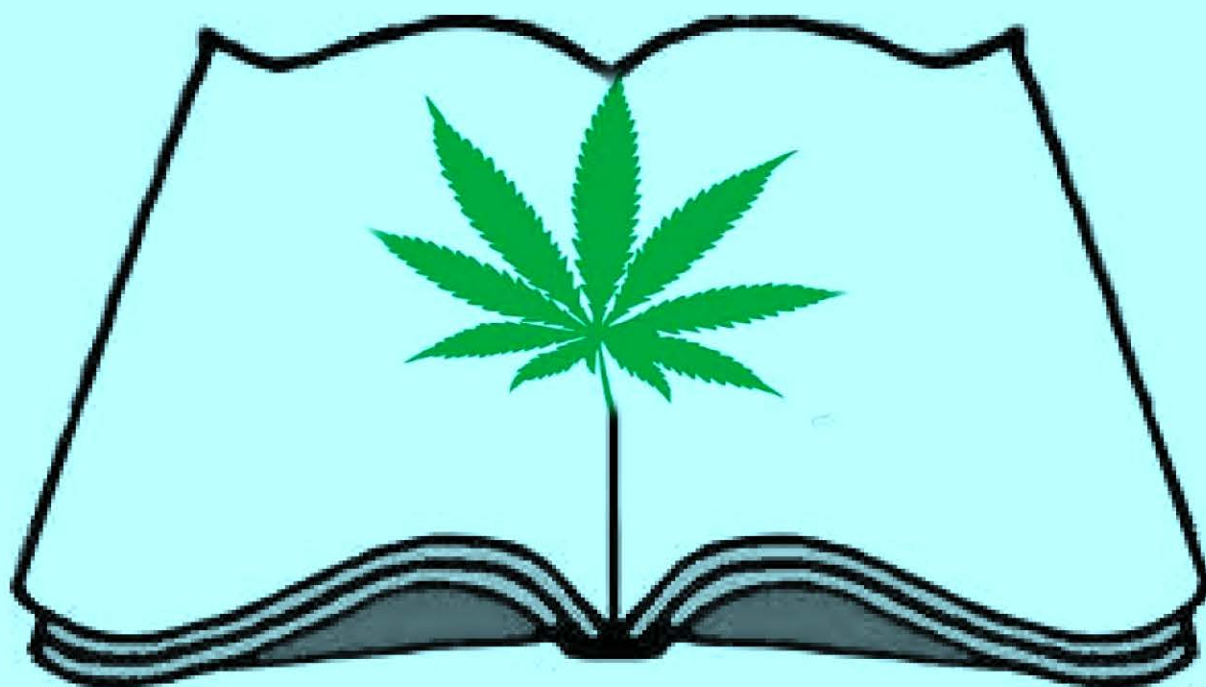




Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material



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GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL

It has been reported that the Indian Patent Office is granting patents on the use of traditional knowledge (TK) of India, particularly relating to the Ayurveda, Unani and Siddha systems of medicine, etc and patents have been granted on inventions related to biological resources obtained from India without taking adequate care to observe the mandate of law. This is inspite of the fact that other international patent offices are denying/objecting to the grant of such patents on the basis of prior art evidence retrieved from the Traditional Knowledge Digital Library (TKDL).

2. 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 centre 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. Further, India has been able to conclude TKDL Access (Non-Disclosure) Agreements with several international patent offices including USPTO, EPO, JPO etc. Consequently, many patent applications concerning India's traditional knowledge have either been cancelled or withdrawn or claims have been amended in several international patent offices. Negotiations are also under way for establishing an international legally binding instrument on protection of TK.

3. Indian law has adequate provisions for the protection of TK and Biological Resources. Traditional knowledge, by its very definition, 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 unique 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 related to TK and/or biological material.

4. On the issue of Biological resources, section 6 (1) of the Biological Diversity Act, 2002 provides very clearly that "no person shall apply 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 obtained from India without obtaining the previous approval of National Biodiversity Authority before making such application; provided that, if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent¹ by the patent authority concerned; provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof. The Indian Patent Law complements this provision of the Biological Diversity Act, 2002 by making it mandatory for the applicant of a patent to submit a declaration under Form-1 (Application for Grant of Patent) of the Patent Rules 2003 to the effect that "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." The Biological Diversity Act, 2002 has a penal provision in this regard under section 55 (1) which provides that "whoever contravenes or attempts to contravene or abets the contravention of the provisions of the section 3 or section 4 or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both."

5. Moreover, applications for patents based on TK and/or biological material contravening the provisions of law can be refused under section 15 or in pre-grant opposition under clauses (d), (f) and (k) of Section 25 (1) and granted patents can be revoked in post-grant opposition under clauses (d), (f) and (k) of Section 25 (2) of the Patents Act, 1970. 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 opposition under clause (j) of Sections 25 (1) and 25 (2) respectively of the Patents Act, 1970.

6. In view of the above facts and the sensitivity and importance of the issue, it is imperative that due care and diligence be exercised while processing patent applications relating to TK and/or biological materials and in post-grant proceedings thereto. Accordingly, the following guidelines are issued for strict compliance by all Examiners and Controllers:

Screening:

7. It should be ensured that all patent applications relating to Traditional Knowledge (TK) are correctly identified, screened and classified as "Traditional Knowledge" by RECS Section. The RECS in-charge should take due care that no case relating to TK is wrongly screened and classified. Additionally, the person in-charge of screening should accord 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 Agrochemicals), C12S, C12N, C07K4/00; 14/00 (for Biotechnology), C12N, C12P, C12Q (for Microbiology), C12F, C12G (for

¹ With effect from 01-01-2005, in the Patents Act, 1970, the process of grant of patent has been modified to replace acceptance and subsequent grant and sealing of patent by a process of grant of patent.

Biochemistry), A23C, A23L (for Food), B25F (for Mechanical), etc. The screening of an application as "Traditional Knowledge" is an administrative process for facilitating the examination and to indicate that the subject-matter of the application is important and has relevance in the context of traditionally known substances, articles or processes for preparing them or their use.

8. In the rare situation that the screening and/or classification by the RECS Section is not found to be appropriate in respect of applications relating to TK during allotment/examination, it should be immediately brought to the notice of the Group Leader by the concerned Examiner/Controller and re-screening and/or re-classification should be done by the Group Leader (GL) forthwith.

9. If an application is wrongly screened and classified as "Traditional Knowledge", only the Technical Head shall be competent for re-screening and/or re-classification of the same to any other screening field on the recommendation of the concerned Group Leader.

10. System Administrator should create separate screening fields in the Module namely, TK-Chemical, TK-Biotechnology and TK-Mechanical.

Allotment:

11. In the concerned Group, the Group Leader shall himself/herself act as the Controller for all applications related to TK. The Group Leader/Controller shall ensure that the provisions related to the protection of TK and/or biological material are fully complied with. The concerned Group Leader shall select one suitable Examiner from within his/her Group for dealing with all applications relating to TK. The concerned Group Leader/Controller and Examiner should endeavor to continuously upgrade their knowledge about TK and/or Biological Resources.

12. Any application/case already under process including pre-grant opposition relating to TK shall be re-allotted to the identified pair in the respective Group. Whenever any Examiner/Controller comes across a case related to TK, he/she shall bring to the notice of GL for re-allotment.

Examination:

13. In every case related to TK and/or biological material, the Examiner shall carry out a thorough search for anticipation in TKDL and/or other databases. If any citation is made from TKDL database, then copy of the citation (English translated) should be sent along with the examination report.

14. Assessment of Novelty and Inventive step:

The patents Act warrants that the subject-matter claimed in a patent application must be novel. The inventive step is another cardinal principle of patentability. Often it is said to be the final gate keeper of the patent system. While considering the traditional knowledge based inventions, the following guiding principles must be followed in assessing the novelty and inventive step:

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 as part of teachings of Traditional Knowledge.

When the subject-matter of claims relate to extracts of plant materials containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or plant materials is pre-known as a part of teaching of TK. However, if the claims relate to alkaloids and/or active principles obtained from the plant materials 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 from the teaching of TK. Thus, 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 extract of *Withania* plant for the management of stress.

Prior art (TKDL): Discloses use of *Withania somnifera* roots and not *Withania* plant extract 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* plant. Based on the prior art, it can be objected that the 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 teaching of prior art obtained from TKDL.

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 (TKDL): 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 isolation and characterization of the same cannot be considered to involve an inventive step in the light of prior art obtained from TKDL.

Guiding Principle 2: Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.

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

Prior art (TKDL): Discloses independent use of *Calendula officinalis*, *Aloe vera* and *Centellae 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).

Illustration 2: Patent application claims relate to a composition comprising Ginger, Radish, Celery and Black seed for enhancing male fertility.

Prior art (TKDL): Discloses independent use of Ginger, Radish, Celery and Black seed as Aphrodisiac and Spermatogenic in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to a composition. Though none of the prior arts disclose a composition comprising a combination of the four extracts as claimed in the present application, it can be objected from prior art documents that the use of the single ingredients ginger, radish, celery and black seed as aphrodisiac and/or spermatogenic is well-known in the prior art.

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.

Illustration 1: Patent application claims relate to a combination of five constituents, one of these being a 1:2 watery extract of *Cucumis melo* containing catalase and superoxide dismutase; along with *Pimienta racemosa*, *Citrus aurantifolia*, Coenzyme Q-10 and Pyridoxine Chlorhydrate for the treatment of vitiligo.

Prior art (TKDL): 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 five 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 merits can not be acknowledged.

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 (TKDL): 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 unpatentable in so far as the alleged invention is obvious over Agasthiyar (TKDL) 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, however the amount of specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill 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 out one single 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 (TKDL): 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: In case individual ingredients are 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 plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).

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

Prior art (TKDL): Discloses use of said plants for the treatment of wound and as a Cicatrizant/healing agent in Ayurveda and Unani systems of medicine.

Analysis: The claim of alleged invention relates to a composition. In view of the prior art, 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).

Illustration 2: Patent application claims relate to a composition comprising of theanine (Tea) and a herb selected from *Sankhapuspi*, *Satavari* or a mixture thereof for the treatment of a disease (cold and/or influenza) related to reduced immunity.

Prior art (TKDL): Discloses independent use of said plants for the treatment of cold and influenza and as immuno-potentiator in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to a composition. In view of the prior art, the use of theanine comprised in tea and extracts thereof, for prevention and/or treatment of cold and/or influenza was known from popular medicine since ages. The immunoadjuvant/immunomodulatory potential of *Asparagus racemosus* (*Satavari*), aqueous extracts/*Evolvulus alsinoides* (*Sankhapuspi*) was also disclosed in prior art documents. Therefore, nothing inventive could be seen in the additional use of immunopotentiating herbs to treat these diseases. A combination of these plants would be obvious as an immuno-potentiator and for the treatment of common cold and a variety of other diseases.

15. While deciding the patentability of the claimed subject matter, the relevant clauses of section 3, particularly sections 3 (c), (e), (i), (j) and (p) of the Patents Act, for TK and/or biological material should be strictly followed.

16. The applications related to TK and/or biological material shall also be 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) of the Patents Act,

17. If the source and geographical origin of the biological material used in the invention is not disclosed in the specification, an objection shall be raised thereof in conformity with section 10 (4) (a) & (b) of the Patents Act.

NBA permission:

18. 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". This provision of declaration in paragraph 9 (in) of Form-1 came into force from 01-01-2005 and every application submitted thereafter should mandatorily have either the affirmative or cancelled out declaration. Where the applicant leaves the declaration unattended, the RECS section should insist upon a fresh Form-1 wherein it should be clearly indicated. If such omission is noted during any stage of processing of the application, the Examiner/Controller should raise an objection in this regard.

19. If the above declaration in Form-1 regarding the use of biological material from India is affirmative, the Examiner/Controller should raise the objection in the FER about the requirement of permission from NBA in the matter, if already not submitted. If the objection has not been raised in the FER, the same may be raised at any stage thereafter. In any case, the patent should not be granted unless the NBA permission is submitted by the applicant.

20. On the other hand, if the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same.

21. Where the declaration in Form-1 is cancelled out but the disclosure in the specification is that the source and/or the origin of the biological material is from India, then NBA permission is required.

22. Therefore, no patent shall be granted without the necessary permission from the National Biodiversity Authority in cases where the invention uses biological material from India or the source and/or the origin of the biological material is from India as per the disclosure in the specification.

23. The directions given in circular No. 1 of 2012 by CGPDTM should be strictly followed, which is reproduced herein below:

It has been observed that during the examination of applications pertaining to the Biological materials diverse yardsticks are adopted by different Patent Officer/Controller as regards the exemption from obtaining permission from NBA in r/o the claimed biological resource in the present application. In view of this, the following directions are issued for strict compliance of the concerned Controllers and Examiners:

“Exemption to medicinal plants from the provisions of the Biological Diversity Act, 2002 given by the notification issued by the Ministry of Environment and forests Notification dated 26th October 2009 is available only if they are traded as commodities and the said provisions are very much applicable if the biological resources are used as ingredients for medicine. As such, any interpretation by the Controllers/Examiners of the Office of CGPDTM to see this as an exemption from the Biological Diversity Act would be wrong.

Controllers/Examiners are directed to ensure strict compliance with the aforesaid order and approval of NBA should be sought for any biological resources derived from India and used in an invention for which patent application is filed.”

Publication of list of TK related patent applications:

24. The System Administrator shall publish the list of all pending patent applications related to TK, which are published under section 11 (A) of the Patents Act, in a separate link on the official website of CGPDTM. This list should be updated automatically on the website as per screening field in the module on real time basis. The list should display at least the following fields: application number, date of filing, title of the invention and name of applicant (indexed in the order of date of filing).

25. A list of patents granted on applications related to TK should also be published on the website for all such patents granted from 1st July 2012. This list should also be updated automatically on the website as per screening field in the module on real time basis. The list should display at least the following fields: application number, patent number, date of filing, date of grant, title of the invention and name of patentee (indexed in the order of date of grant).

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