

# INVENTOR GUIDANCE NOTES

(While papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)



<b>TOPIC:</b> <b>TRADITIONAL KNOWLEDGE , BIODIVERSITY GUIDELINES on PATENT FILINGS IN INDIA</b>	<b>AUTHOR:</b> <b>SNEHA KANITKAR</b> <b>A207, PAML</b> <b>National Chemical Laboratory</b> <b>Pune – 411008</b> <b>Phone: +91-20-2590-2757</b> <b>Email: sv.kanitkar@ncl.res.in</b>
<b>IGN Number:</b> <b>IGN-09</b>	<b>VERSION:</b> <b>01</b>
<b>SCOPE:</b> <b>This Inventor Guidance Notes provides information for scientists regarding the impact of traditional knowledge &amp; biodiversity guidelines on patenting life-sciences related inventions in India.</b>	<b>DATE:</b> <b>15<sup>th</sup> May 2013</b>
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## A. SUMMARY:

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. 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 1970.

Sr no	Certain Guiding Principles for TK related inventions	Examples	TK Reference/ prior art
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.	<a href="#">1319/CHE/2013</a> Evaluation of anticancer properties of acahypha alnifolia klein ex willd - in vitro and in vivo	<a href="#">ME02/97 Rasaganthi Mezhugu</a> Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15 <sup>th</sup> Century A.D  [relevant prior art in opinion of IGN authors]
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.	<a href="#">31/DEL/2008</a> A herbal extract obtained from the roots of burcea mollis	E O Ajaiyeoba et al., 'In vivo antimalarial activities of Quassia amara and Quassia undulate plant extracts in mice', Journal of Ethnopharmacology, Vol 67, Issue 3, 1999, 321-325 (Nigerian folk medical practices)
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.	<a href="#">218/DEL/2006</a> A novel herbal composition effective against coryza and a process for preparing thereof	Divya Swasari Kvath 100gm, Produced by: ( Divya Yog Mandir (Trust), Swami Ramdev ).
4.	Discovering the optimum or workable ranges of traditionally known ingredients by routine experimentation is not inventive.	<a href="#">1576/DEL/ 2006</a> Novel herbal composition effective against skin disorders and to a process for the preparation thereof	BA3/465 Hab Deedan ; BA3/478 Hab Barg-e- Neeb ; BA4/1745 Nuskha Dawa; BA4/1745A Habb Musaffi-e-khoon ; BA4/1754 Nuskha Naqoo ; Nature Heals, A glossary of selected indigenous medicinal plants of India.
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.	<a href="#">1319/CHE/2013</a> Evaluation of anticancer properties of acahypha alnifolia klein ex willd - in vitro and in vivo	<a href="#">ME02/97 Rasaganthi Mezhugu</a> Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15 <sup>th</sup> Century A.D [relevant prior art in opinion of IGN authors]
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).	<a href="#">1076/CHE/2007</a> A synergistic ayurvedic/functional food bioactive composition (cincata) and a process of preparation thereof	W00172316

The Biological Diversity Act, 2002 provides mechanism for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty.

## B. RELEVANT LEGAL EXTRACTS:

<b>INDIA : THE PATENT ACT, 1970</b>	
<b>Section 2 (1) (j)</b>	Defines invention as: "invention means a new product or process involving an inventive step and capable of industrial application".
<b>Section 3(e)</b>	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.
<b>Section 3 (p)</b>	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.
<b>INDIA: BIODIVERSITY ACT, 2002</b>	
<b>Section 6</b>	<p>(1) 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 the National Biodiversity Authority before making such application:</p> <p>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 patent by the patent authority concerned:</p> <p>Provided further that the National Biodiversity shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.</p> <p>(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.</p> <p>(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.</p> <p>(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.</p>

### C. INTERPRETATION OF THE LAWS AND EXPLANATION:

#### Interpretation of the laws:

##### Traditional knowledge:

TK, 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.

Illustrative example:

Claim: Serum of pigeon possessing the anti-paralysis activity.

Analysis: The use of pigeon serum for the treatment of paralysis (as it possesses anti-paralytic activity) is a traditional knowledge in India or is an aggregation or duplication of known properties of traditionally known component. It is clearly evident from prior art (Mahawar et al., "Animals and their products utilized as medicines by the inhabitants surrounding the Ranthambhore National Park, India", Journal of Ethnobiology and Ethnomedicine, 2006, 2:46), which discloses the use of pigeon blood for treating paralysis.

While considering the traditional knowledge based inventions, the following guiding principles must be followed in assessing the novelty and inventive step<sup>5</sup>:

Sr no	Guiding Principle	Illustration	Prior art	Analysis
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.	Patent application claims relate to an extract of <i>Withania</i> plant for the management of stress.	Discloses use of <i>Withania somnifera</i> roots and not <i>Withania</i> plant extract for the treatment of stress related disorders in Ayurveda and Unani systems of medicine.	The claims of alleged invention relate to an extract of <i>Withania</i> plant. Based on the prior art, it can be objected that the extract of <i>Withania somnifera</i> 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.

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.	Patent application claims relate to a composition comprising of Calendula officinallis, Aloe vera and Centellae asiatica as healing agent and for treatment of wound.	Discloses independent use of Calendula officinallis, Aloe vera and Centellae asiatica for the treatment of wound and as a Cicatrizant/healing agent in Ayurveda and Unani systems of medicine.	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).
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.	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.	Discloses usefulness of only one of the constituents, watery extract of Cucumis melo for its anti-vitiligo property in the Unani system of medicine.	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 cannot be acknowledged.
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	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	Discloses use of said plants for the treatment of ulcer/wound in Ayurveda, Unani and Siddha systems of medicine.	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

	selection of optimum or workable range is well within the expectation of a person skilled in the art.	Datura 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.		in the art would routinely optimize.
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.	Patent application claims relate to an extract of Zingiber zerumbet (bitter ginger) for inflammation and also for allergic disorder like Asthma.	Discloses use of Zingiber zerumbet (bitter ginger) along with few other ingredients for the treatment of inflammation and Asthma in Unani system of medicine.	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.
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).	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.	Discloses independent use of said plants for the treatment of cold and influenza and as immuno-potentiator in Ayurveda and Unani systems of medicine.	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 immunopotentiator and for the treatment of common cold and a variety of other diseases.

### BIODIVERSITY RELATED ISSUES

Biodiversity related matters play a vital role in the patentability of the biological substances. The Biological Diversity Act, 2002 provides mechanism for conservation of

biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto.

In order to prevent misappropriation of biological resources and traditional knowledge of India, the Biological Diversity Act requires that access to the biological resources of India is subject to the equitable benefit sharing through the approval of National Biodiversity Authority (NBA). No Intellectual Property Rights (IPRs), including patents based on research or information on biological resources obtained from India shall be granted without the approval of the NBA.

The Patents Act provides interfaces with the process of obtaining patents and access to and benefits sharing from utilization of Indian biological resources. Thus, disclosure of the source and geographical origin of a biological material used in an application for a patent has been made mandatory as per Section 10 (4) of the Act. Also, as already discussed Section 3 (p) of the Act prohibits patenting of any invention which, in effect, is traditional knowledge.

### **DEPOSIT OF BIOLOGICAL MATERIAL**

If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.

Depository Authorities: Reference to IDA under the Budapest Treaty under Section 10 (4) should be read with Section 2 (1) (aba) of the Act.

## D. EXAMPLES & CASES:

### 1. Patents applications classified as under traditional knowledge

Sr No.	Patent No & Title	Status	Claims	Basis for classification	TK reference/ Prior art
1	<a href="#">1319/CHE/2013</a> Evaluation of anticancer properties of acalypha alnifolia klein ex willd - in vitro and in vivo	Application awaiting examination	The plant <i>Acalypha alnifolia</i> plant belongs to the Euphorbiaceae. <ul style="list-style-type: none"> <li>The plant is low cost and easily available.</li> <li><i>Acalypha alnifolia</i> plant extract have antioxidant property, where it can cure more than 200 diseases.</li> <li><i>Acalypha alnifolia</i> plant extract also have the cytotoxicity activity against different cell line.</li> <li>It is active in prostate cancer cell line, liver cancer cell line, vero cancer cell line, DLA cell line and normal cell line.</li> <li>The plant extract also shows the anticancer property.</li> </ul>	<ul style="list-style-type: none"> <li>Plant patents are not allowed in India</li> <li>-Guiding principle 1- As the subject-matter 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.</li> <li>- Guiding principle 5- 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.</li> </ul>	<a href="#">ME02/97 Rasaganthi Mezhugu</a>  Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15 <sup>th</sup> Century A.D
2	<a href="#">1576/DEL/2006</a> A novel herbal composition effective against skin disorders and to a process for the preparation thereof	Application refused grant of a patent	1.A herbal composition effective against skin disorder comprising of: i) seeds of Maghz-e-Nimkoli ( <i>Azadirachta indica</i> A. Juss) 150-175mg ii) roots of Rasaut ( <i>Barberis asatica</i> Raxb) 150-175mg iii) whole plant of Chaksu ( <i>Cassia absus</i> Linn) 150-175mg 2. A process for the preparations of a herbal composition effective against skin disorder comprising in the steps of separately preparing an extract of Neem, Rasaut bark, and Chaksu and mixing the three extracts, kneading for half hour, kneaded mass is dried at 85°C for 3 hours, evaporated in hard gelatin capsule.	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.  Although the cited references do not specifically teach adding the ingredients in the amounts claimed by the applicant, however the references does teach the ingredients Maghz-e-Nimkoli, Rasaut and Chaksu as a composition to treat skin disorders. This reasonable expectation of success would motivate an artisan of ordinary skill to use the said plant parts for reaching at the claimed composition. The amount of a specific ingredient in a composition that is used for a particular purpose is a result effective parameter that a person having ordinary skill in the art would routinely optimize. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. It would have been customary for an artisan of ordinary skill to determine the optimum amount of each ingredient to add in order to best achieve the desired results.	BA3/465 Hab Deedan ; BA3/478 Hab Barg-e-Neeb ; BA4/1745 Nuskha Dawa; BA4/1745A Habb Musaffi-e-khoon ; BA4/1754 Nuskha Naqoo ; MA3/122 Habb-e-Surkhbada; MA3/160 Habb-e- Musaffi-e-khoon Ba Nuskha Khaas ; MH1/2352 Hab Bara-e-Ishaal-e- Atfaal ; MH1/2352A Hab Barae Ishaal-e- Atfaal – A ; NA4/1027 Khesanda Surkhbada ; NA4/4068 Hab Barae Deedaan Deegar Qawitar ; NA4/4083 Habb-e-Bawaaseer Khooni ; Nature Heals, A glossary of selected indigenous medicinal palants of India, SRISTI Innovations Second Edition - February 2002 First Published by SRISTI Innovations October



					1997
3	<a href="#">31/DEL/2008</a> A herbal extract obtained from the roots of <i>Brucea mollis</i>	Application refused grant of a patent	1.A herbal extract obtained from the roots of <i>Brucea mollis</i> , wherein the extract has antiparasmodial activity. 2. An extract as claimed in claim 1, wherein the extract is methanolic-chloroform, methanolic-aqueous, petroleum ether or water extract.	The cited references teach <i>Brucea</i> plant having antiparasmodial activity although not exactly <i>Brucea mollis</i> . If one species of the plant possesses antiparasmodial activity, there shall be reasonable expectation of success and motivation for a skilled artisan to use another species of the said plant part for testing the antiparasmodial activity. The cited prior arts teach methanolic chloroform and methanolic aqueous extracts of <i>Brucea mollis</i> roots. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover merely another species having same activity by routine experimentation. D4 discloses that plant family Simaroubaceae is well known for its antimalarial properties in Nigerian folkmedical practices and elsewhere. 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.	E O Ajaiyeoba et al., 'In vivo antimalarial activities of <i>Quassia amara</i> and <i>Quassia undulata</i> plant extracts in mice', Journal of Ethnopharmacology, Vol 67, Issue 3, 1999, 321-325 (Nigerian folk medical practices)
4	<a href="#">1076/CHE/2007</a> A synergistic ayurvedic/functional food bioactive composition (cincata) and a process of preparation thereof	Patent Revoked	1.A synergistic ayurvedic / functional food bioactive composition for managing diabetes and related disorders, said composition comprising extracts of atleast two plants selected from a group comprising <i>Eugenia</i> , <i>Cinnamomum</i> and <i>Salacia</i> optionally along with pharmaceutically acceptable excipients.	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).	WO0172316
5	<a href="#">218/DEL/2006</a> A novel herbal composition effective against coryza and a process for preparing thereof	Granted Application , Patent Number : 249186	1.A novel herbal composition effective against coryza (Common Cold) comprising of Barg-e-Tulsi ( <i>Ocimum Sanctum</i> Linn.) in an amount of 90-125 mg, Darchini ( <i>Cinnamomum Zeylanicum</i> Blume) in an amount of 90-125 mg, Satte Ajwani ( <i>Ptychotic ajowan</i> DC) in an amount of 95-105 mg, Zanjabeel ( <i>zingiber officinale</i> Rose) in an amount of 90-125 mg and Satte Gilo ( <i>Tynospora cordifolia</i> willd) in an amount of 95-130 mg.	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.	P Prakash, N Gupta - Indian journal of physiology and pharmacology, 2005, 49(2) : 125 -131  Divya Swasari Kvath 100gm, Produced by: ( Divya Yog Mandir (Trust), Swami Ramdev ).

## 2. Case studies related to Traditional knowledge & Biodiversity related inventions:

Case Study No: TK/01/Jeevani

The Drug	Traditional Knowledge	Intellectual Property	Benefit Sharing Model
"Jeevani" is a restorative,	"Jeevani" drug, was developed by	The knowledge was divulged by three Kani tribal	A Trust Fund was established to share

<p>immunoenhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant <i>arogyapaacha</i>, used by the Kani tribals in their traditional medicine</p>	<p>scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe in Kerala, South India. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribal healers, known as <i>Plathis</i>.</p>	<p>members to the Indian scientists who isolated 12 active compounds from <i>arogyapaacha</i>, developed the drug "Jeevani", and filed two patent applications on the drug (and another patent based on the same plant but for different use). The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations.</p>	<p>the benefits arising from the commercialization of the TK-based drug "Jevaani". Half of the royalties and license fees from the sale of 'Jeevani' are paid to the Kani in recognition of their intellectual property rights. It is one of the few cases in India where traditional knowledge has been rightly respected and paid for.</p>
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**Case Study No: TK/02/ Jamun**

The Patent	Claims	The case	The verdict
<p>A patent was granted for "synergistic ayurvedic/ functional food bioactive composition". Patent application no 1076/ CHE/ 2007 was for the composition consisting of jamun, lavangpatti and chundun and this composition was to be used for treatment of diabetes</p>	<p>A synergistic ayurvedic / functional food bioactive composition for managing diabetes and related disorders, said composition comprising extracts of atleast two plants selected from a group comprising <i>Eugenia</i>, <i>Cinnamomum</i> and <i>Salacia</i> optionally along with pharmaceutically acceptable excipients.</p>	<p>Avesthagen filed for a patent in European Patent Office (EPO) for the above said composition but when the examiners checked the patent with TKDL database, they provided a report due to which the patent was not granted. The report said that patent did infringe upon TKDL. CSIR had made individual intervention for the same. In April 2012, a patent was granted to Avesthagen and this was the same patent which was rejected by EPO. IPO said that they did not have access to TKDL database that is why their examiners approved the patent.</p>	<p>In a first victory in India, Traditional Knowledge Digital Library (TKDL) database has been used to revoke a patent. Government of India revoked the patent granted to Avesthagen by Indian Patent Office (IPO) in April, 2012 on the grounds of being mischievous and prejudicial to the public. Government on getting knowledge about the same revoked patent using Section-66 of Patents Act, 1970 which is: <b><i>Revocation of patent in public interest- Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.</i></b> Government of India stated in revocation that the use of Jamun for the treatment of diabetes have been long known to India and thus the extract of Jamun will also give effective therapeutic activity for diabetes. Thus, this patent infringes on TK knowledge of India</p>

**Case Study No: TK/03/ Turmeric**

<b>Traditional Knowledge</b>	<b>Intellectual property Claimed</b>	<b>The case</b>	<b>The Verdict</b>
<p>The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and dyes. As a medicine, it has been traditionally used for centuries to heal wounds and rashes.</p>	<ol style="list-style-type: none"> <li>1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient.</li> <li>2. The method according to claim 1, wherein said turmeric is orally administered to said patient.</li> <li>3. The method according to claim 1, wherein said turmeric is topically administered to said patient.</li> <li>4. The method according to claim 1, wherein said turmeric is both orally and topically administered to said patient.</li> <li>5. The method according to claim 1, wherein said wound is a surgical wound.</li> <li>6. The method according to claim 1, wherein said wound is a body ulcer.</li> </ol>	<p>In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric in wound healing. The Council of Scientific &amp; Industrial Research (CSIR), India, New Delhi filed a re-examination case with the US PTO challenging the patent on the grounds of existing of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent.</p>	<p>The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.</p>

**Case Study No: TK/04/ Neem**

<b>Traditional Knowledge</b>	<b>Intellectual property Claimed</b>	<b>The case</b>	<b>The Verdict</b>
<p>Neem extracts can be used against hundreds of pests and fungal diseases</p>	<p>Since the 1980s, many neem related process and products have been patented in Japan, USA and European countries. The first US patent was obtained by Terumo Corporation in 1983 for its therapeutic preparation from neem bark. In 1985 Robert Larson from (USDA) obtained a patent</p>	<p>In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company</p>	<p>In 1999, the EPO determined that according to the evidence all features of the present claim were disclosed to the public prior to the</p>

<p>that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis</p>	<p>for his preparation of neem seed extract and the Environmental Protection Agency approved this product for use in US market. In 1988 Robert Larson sold the patent on an extraction process to the US Company W.R. Grace (presently Certis). Having gathered their patents and clearance from the EPA, four years later, Grace commercialized its product by setting up manufacturing plant in collaboration with P.J. Margo Pvt. Ltd in India and continued to file patents from their own research in USA and other parts of world. Aside from Grace, neem based pesticides were also marketed by another company, AgriDyne Technologies Inc., USA, the market competition between the two companies was intense. In 1994, Grace accused AgriDyne a non-exclusive royalty-bearing license. During this period in India large number of companies also developed stabilized neem products and made them available commercially. The number of patents filed in this period were limited and geographically confined to few countries.</p>	<p>and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995, a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and therefore, was unpatentable.</p>	<p>patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000. EPO, in March 2006, rejected the challenge made in 2001 by the USDA and the chemicals multinational, W. R. Grace to the EPO's previous decision to cancel their patent on the fungicidal properties of the seeds extracted from the neem tree.</p>
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**Case Study No: TK/05/Ginger**

Application details	The Invention	Claims	The case	Traditional knowledge cited as prior art
<p>A patent specification titled "Pharmaceutical composition for the treatment of excess mucous production" was filed at British Patent Office having a patent priority</p>	<p>The british patent application discloses a composition comprising ginkgo biloba or extract or component thereof; apocynin; and a gingerol. The composition may be used to treat diseases such as Cystic fibrosis (CF) and Chronic obstructive pulmonary disease (COPD).  The patent applicant found that compositions according to the invention may have a remarkable effect in reducing excessive mucous production, especially excessive pulmonary mucous production. Moreover, the use of a gingerol (or</p>	<p>The important patent claims of the patent application are as follows:</p> <ol style="list-style-type: none"> <li>1. A composition comprising ginkgo biloba or extract or component thereof; apocynin; and a gingerol.</li> <li>2. A composition according to claim 1 wherein the gingerol is in the form of a natural gingerol.</li> <li>3. A composition according to claim 1 or claim 2 wherein the gingerol is in the form of Zingiber Officinale.</li> </ol>	<p>Zingiber Officinale is the scientific name for ginger and commonly known as adrak in India. Ginger has been used as medicinal remedy for cough and cold since ages in India. Moreover, the medicinal properties of ginger has been the traditional knowledge of India.  Consequently, the department of AYUSH and Council of Scientific and Industrial Research (CSIR) intervened and provided evidence from age-old ayurveda and unani books, dating back to the 18th century that talked about ginger to treat cough and</p>	<p>The books that were referred to as evidence by CSIR included Ilaaj-al-Amraaz (18th century), Bhaishajya Ratnavali and Bharata Bhaishajya Ratnakara (1000 BC),</p>

<p>date of March 16, 2006 by the inventor Nicholas John Larkins.</p>	<p>gingerols) in combination with ginkgo biloba (or extract or component thereof) and apocynin provided a substantial clinical improvement; and especially a substantial reduction in excessive mucous production. It is apparent that there is a synergistic clinical outcome when a gingerol (or gingerols) is added to a preparation comprising ginkgo biloba (or standardised extract or component thereof), and apocynin.</p>	<p>5. A composition according to any preceding claim comprising gingerol in the form of isolated gingerol.</p> <p>23. A method of treatment or amelioration of disease by reduction of excessive mucous production comprising the step(s) of administering to the subject a composition comprising ginkgo biloba, or extract or component thereof; apocynin; and a gingerol.</p>	<p>other diseases.</p> <p>Patent prior art knowledge was retrieved from the Traditional Knowledge Digital Library (TKDL) database of India and submitted at the UK patent office. Subsequently, the patent examiner took into consideration of the prior art traditional knowledge of India and rejected the patent application for the ginger based pharmaceutical composition for the treatment of excess mucous production.</p>	<p>Bayaaz-e-Kabir (1938 AD), Muheet-e-Azam (19th century) and Khazaain-al-Advia from the 18th century.</p>
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**Case Study No: TK/06/Basmati**

<b>The case</b>	<b>Intellectual property claimed</b>	<b>The Opposition</b>	<b>The verdict</b>
<p>Rice Tec. Inc. had applied for registration of a mark "Texmati" before the UK Trade Mark Registry. Agricultural and Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest.</p>	<p>This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The US PTO granted the patent to Rice Tec on September 2, 1997. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced.</p>	<p>Evidence from the IARI (Indian Agricultural Research Institute) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. CFTRI (Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics.</p>	<p>Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15-17 along with claim 4.</p>

## E. REFERENCES:

1. The Patent Act, 1970
2. Draft Manual of Patent practice & procedures, The Patent Office India
3. Protection of Plant Varieties and Farmers' Rights Act, 2002
4. Biodiversity Act 2002
5. [http://www.ipindia.nic.in/iponew/TK\\_Guidelines\\_18December2012.pdf](http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf)
6. [http://www.ipindia.nic.in/whats\\_new/biotech\\_Guidelines\\_25March2013.pdf](http://www.ipindia.nic.in/whats_new/biotech_Guidelines_25March2013.pdf)
7. <http://ipindiaservices.gov.in/tk/>
8. [www.tkdil.res.in](http://www.tkdil.res.in)
9. <http://www.indiankanoon.org/doc/1905157/>
10. [http://www.ipfrontline.com/downloads/Nitin\\_Shukla\\_TKDL.pdf](http://www.ipfrontline.com/downloads/Nitin_Shukla_TKDL.pdf)
11. <http://biotechpatentattorney.wordpress.com/2012/01/04/traditional-knowledge-of-india-on-ginger-rejected-by-the-british-patent-office/>
12. <http://ipindiaservices.gov.in/patentdecisionsearch/patentsearch.aspx>
13. [http://articles.timesofindia.indiatimes.com/2012-01-04/delhi/30588073\\_1\\_bhaisajya-ratnavali-tkdil-traditional-knowledge-digital-library](http://articles.timesofindia.indiatimes.com/2012-01-04/delhi/30588073_1_bhaisajya-ratnavali-tkdil-traditional-knowledge-digital-library)
14. <http://www.iimahd.ernet.in/publications/data/2002-08-02AnilKGupta.pdf>
15. <http://www.tkdil.res.in/tkdil/langdefault/common/Biopiracy.asp>
16. <http://www.iipta.com/ipr/blog/avesthagen-patent-revoked-1005>

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**Note:** This IGN was finalized in the current form on 21<sup>st</sup> Aug 2013. This is intended as a working document. Readers are requested to provide comments/suggestions & point to any errors (if any) so as to help improve this document. Comments may be sent to [sv.kanitkar@ncl.res.in](mailto:sv.kanitkar@ncl.res.in)