

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)

Traditional Knowledge Digital Library (TKDL) is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Ministry of Health and Family Welfare.

TKDL involves documentation of the knowledge available in public domain on traditional knowledge from the existing literature related to Ayurveda, Unani and Siddha in digitized format, in five international languages which are English, French, German, Spanish and Japanese. So far, the TKDL includes about 2.12 lakh medicinal formulations (Ayurveda: 82,900; Unani: 1,15,300; Siddha: 12,950), from 148 books available in public domain, and the database exists in 34 million A4 size pages. Creation of TKDL – Yoga is under process and till date about 900 no. of Yoga postures from 14 old yoga books in public domain have been transcribed, which will also be videographed and added to TKDL database.

Government of India, on 29th June 2006, has approved to provide the access of TKDL database to International Patent Offices, under Non-disclosure Agreement, between CSIR and respective International Patent Office, according to which -

- (i) Access to TKDL by the examiners of an international patent office would only be utilized for patent search and examination, and
- (ii) International Patent Offices and their examiners would not make any third party disclosure other than what is necessary and essential for the purpose of patent search and examination.

Access to TKDL has been given to European Patent Office (having 35 member states), German Patent Office, Indian Patent Office and United States Patent and Trademark Office (the Agreement for which was signed in November 2009, on the sidelines of the State visit of Hon'ble Prime Minister to United States).

The genesis of the maiden Indian effort dates back to the year 2000, when an interdisciplinary Task Force of experts was set up by Department of AYUSH and CSIR, to devise a mechanism on protection of India's Traditional Knowledge, after the wrong patents granted on the wound healing properties of turmeric (US patent No. 5,401,504) by USPTO and on the bio-pesticidal property of Neem (EPO patent No. 436257) by EPO, came to notice which were later fought and got revoked. Pursuant to this, studies were carried out to

find out the extent of misappropriation of India's traditional knowledge which show that there is a continuous rise in misappropriation of traditional medicinal knowledge of India at the International Patent Offices, as reflected in the table below,

| S.No | Patent Databases Studied | Year of Study | No. of patents taken |
|-------------|---------------------------------|----------------------|-----------------------------|
| 1 | USPTO | 2000 | 4,896 |
| 2 | International Patent Offices | 2003 | 15,000 |
| 3 | -----do----- | 2005 | 35,567 |
| 4 | -----do----- | 2008 | 85000 |

Number of patents taken on Indian Systems of Medicine at International Patent Offices each year is approx.2000.

With reference to Yoga, the study conducted by the TKDL team on the international patent databases in February 2004 found 249 patents taken on Yoga, in May, 2005 found over 2300 patents, 2315 Trademarks at USPTO and nearly 150 copyrights at USPTO, taken on Yoga

The reason for this misappropriation at International Patent Offices, as identified, is that the traditional medicinal knowledge exists in local languages, such as Sanskrit, Urdu, Arabic, Persian and Tamil which is neither available nor can be understood by patent examiners even in case of availability, at international patent offices since the information exists in local languages. In other words, there exists a language and format barrier due to which patents are being taken on the existing traditional knowledge of India. To break this language and format barrier Traditional Knowledge Digital Library (TKDL) was created by India, which with the help of Information Technology tools and a novel classification system i.e., Traditional Knowledge Resource Classification (TKRC), makes the knowledge available to patent examiners in patent application format and in a language that can be understood by them.

TKDL has enabled inclusion of approx. 200 subgroups instead of few subgroups available earlier in the International Patent Classification (IPC). The decision was taken in 35th IPC Union Meeting of World Intellectual Property Organization (WIPO) on the initiative of India. This is likely to have significant impact on the system of search and examination while granting patents in the area of traditional knowledge whereby the possibilities of grant of wrong TK patents shall get significantly reduced.

International specifications and standards for setting up of TK databases and registries have been established based on TKDL specifications, which were adopted by the Intergovernmental Committee (IGC) of WIPO on Intellectual Property and Genetic Resources, Traditional Knowledge and Expression of folklore in its fifth session held in 2003.

The TKDL Access Agreements are unique and would have long-term implications on the protection of traditional knowledge and global intellectual property systems. The impact of TKDL Access agreement with EPO may be appreciated due to the fact that generally, a patent opposition process involves an average time of 10-12 years and expenses running into millions of US dollars. For example, the opposition process in the cases of Neem Patent (EP436257), Enola beans patent (US Patent No. 5894079) and Monsanto Soybean patent (EP301749) took 10 years in each of the first two cases and 13 years in the third case, when the final decision on rejection could arrive. On the other hand, with the help of TKDL, opposition communicated in the form of 'Third party observation' against patent applications filed on India's traditional knowledge at EPO, shows the impact in few weeks of time without any cost implications. In fact now cancellation happens at international patent office based on e-mail from TKDL, unit CSIR. For example, based on the examination carried out by the TKDL team on the patent applications filed at the EPO and the TKDL database, CSIR had submitted 'Third party observations' in 36 cases where patent applications were filed on India's TK, giving evidences from TKDL for the misappropriation. In response, EPO has set aside intention to grant patent in two of the cases, whereas six patent applications have been withdrawn by the applicants on receiving details of *prior art* available in TKDL, from EPO. Similar results are expected at USPTO and other patent offices where CSIR has been able to conclude the Access Agreement.

The access to the TKDL for International Patent Offices would also enhance the negotiating strengths of India and the developing countries at the international fora. In fact, the international IP community has recognized TKDL as the effective tool for protection of traditional knowledge. In a recent communication, the Director General, World Intellectual Property Organization has recognized TKDL as a strong practical tool which has made unparalleled contributions to the international policy context of the patent systems by offering a template for other countries who seek to protect their own traditional knowledge. EPO has described TKDL as a unique encyclopedia which is very precise and shall prevent bio-prospectors from digging up ancient medical wisdom and laying claim upon them. EPO has acknowledged that with TKDL, examiners have improved access to background information

at an early stage of patent examination vis-a-vis a scenario where a patent may have been granted and the countries had to present evidence against it. USPTO considers TKDL as a part of the very important work being done internationally with respect to TK databases

Several countries and organizations such as South Africa, African Regional Industrial Property Organization (ARIPO), Mongolia, Nigeria, Thailand, Malaysia have shown interest for creating their own TKDL based on TKDL created by India for protecting their own traditional knowledge.

Effectiveness and impact of TKDL access agreement with European Patent Office (Feb 2009)

The TKDL access agreement was concluded with European Patent Office in February 2009, as a mutually beneficial agreement, since it enhances the quality of examination for TK based patent applications for EPO and it prevents misappropriation for India.

So far 35 patent applications based on Indian traditional medicinal knowledge have been identified, being processed at European Patent Office, wherein in our opinion no novelty or innovation exists. Third party observations against these patent applications have been filed, quoting relevant references from TKDL. Since then in two cases EPO has set aside its intention to grant patent and in other six cases applicant(s) have decided to withdraw their applications on receiving information about *prior art* existing in TKDL, from EPO. Remaining 27 cases are under examination at EPO. Details of the cases are given below.

A. Cases where intention to grant has been set aside:

EP1747786 (3 Weeks)

Title: Natural product in cream with anti-vitiligo therapeutic properties

Applicant & Country: PERDIX EUROGROUP S L, Spain

Key dates:

Filing: 24-July-2006

Intention to grant: March-2009

TKDL Evidence Sent: 08-July-2009

Setting aside intention to grant: 28-July-2009

***Description in Annex - A**

EP1520585 (1 Week)

Title: Cancer treatment using natural plant products or essential-oils or components from some pistacia species

Applicant & Country: DATA MEDICA PADOVA S P A, Italy

Key dates:

Filing: 24-Sept-2004

Intention to grant: 19-Feb-2009

TKDL Evidence Sent: 09-July-2009

Setting aside intention to grant: 14-July-2009

***Description in Annex - B**

B. Cases where applicants decided to withdraw their applications

EP1607006 (3 Weeks)

Title: Functional berry composition

Applicant & Country: UNILEVER NV, Netherland

Key dates:

Filing: 18-June-2004

TKDL Evidence Sent: 17-July-2009

Unilever withdrew its application: 04-August-2009

***Description in Annex - C**

EP1781309 (9 Weeks)

Title: nelumbinis semen extract for preventing and treating ischemic heart disease and pharmaceutical composition and health food containing the same

Applicant & Country: Purimed Co., Ltd. Seoul, Korea

Key dates:

Filing: 09-June-2005

TKDL Evidence Sent: 17-July-2009

Applicant withdrew the application : 18-Sept-2009

***Description in Annex – D**

EP2044850 (9 Weeks)

Title: Method for altering the metabolism characteristic of food products

Applicant & Country: Clara's ApS, Denmark

Key dates:

Filing: 19-Sept-2007

TKDL Evidence Sent: 25-Aug-2009

Applicant withdrew the application : 30-Oct-2009

***Description in Annex – E**

EP1889638 (23 Weeks)

Title: Medicaments and food for treatment or prevention of obesity and/or diabetes containing Cicer arietinum extract

Applicant & Country: Jumpsun Bio-Medicine (Shanghai) Co., Ltd, China

Key dates:

Filing: 06-March-2006

TKDL Evidence Sent: 11-June-2009

Applicant withdrew the application : 20-Nov-2009

***Description in Annex – F**

EP1807098 (21 Weeks)

Title: herbal compositions for treatment of diabetes

Applicant & Country: Amcod Limited, Mombasa, Kenya

Key dates:

Filing: 13-Sept-2005

TKDL Evidence Sent: 01-July-2009

Applicant withdrew the application : 24-Nov-2009

***Description in Annex – G**

EP1967197 (19 Weeks)

Title: Use of preparations, purifications and extracts of aloe

Applicant & Country: Cognis IP Management GmbH, Germany

Key dates:

Filing: 09-March-2007

TKDL Evidence Sent: 20-July-2009

Applicant withdrew the application : 27-Nov-2009

***Description in Annex – H**

C. Normal opposition cases without support of TKDL

Neem (10 years)

EPO Patent No: EP436257
Applicant & Country: Thermo Trilog Corporation, 9145 Guilford Road Columbia, Maryland 21046-1883, USA

Key Dates:

Date of Grant: 4th August 1994
Date of opposition: 14th September 1995
Date of Revocation: 8th March 2005

Monsonito Soybean (13 years)

EPO Patent No: EP301749
Applicant & Country: Monsonito Company, 800 North Lindbergh Boulevard, St. Louis, Missouri 63167, USA.

Key Dates:

Date of Grant: 2nd March 1994
Date of Opposition: 6th October 1994
Date of Rejection: 6th July 2007

Enola bean (10 years)

US Patent No: 5894079
Applicant & Country: Larry M Proctor, Delta Co., USA

Key Dates:

Date of Grant: 13th April 1999
Date of Opposition: 20th Dec 2000
Date of Rejection: 10th July 2009

D. Time and Cost Effectiveness of TKDL

Generally a patent opposition takes an average time of 10-12 years and involves expenses running into millions of US dollars. On the other hand, TKDL access agreement with EPO has created an institutional mechanism whereby either applicants withdraw their application or EPO sets aside its intention to grant patent within 2/3 weeks of getting TKDL prior art evidence. Furthermore, this does not have any cost implications to India and/or European Patent Office.

E. Cases which are under examination and are likely to be cancelled or applicants may withdraw applications:

USA

- Asthma/allergy therapy using Nigella sativa
- Method of treatment or management of stress
- Hydroxylated Polymethoxyflavone Compositions
- Agents for sequestering serum aging factors and uses therefore
- Cosmetic herbal compositions
- Composition and method for facilitating the healing of non-healing and slow-healing wounds and ulcerations
- Compositions for diabetes treatment and prophylaxis

- Bioactive compositions from theaceae plants and processes for their production and use
- Compositions of bakuchiol and methods of making the same
- Methods of Treating Epiphora

Japan

- Anti-Inflammatory Agent
- Skin aging-preventing or improving agent
- Sleep-Improving Composition
- Composition for treating hepatitis c
- Senescence Inhibitor

Great Britain

- Treatment of inflammatory bowel disease
- Polyphenol Extraction Process
- Method and system for producing medicinal alcohol as a prophylactic or remedy for cancer, HIV, AIDS and autoimmune diseases

Italy

- A process for the preparation of ferutinine from ferula genus plants
- Cancer treatment using natural plant products or essential oils or components from some pistacia species
- Methods and composition for treating sore throat Applicant

Germany

- Use of preparations, purifications and extracts of aloe
- Skin treatment composition

India

- Biotherapeutics for mitigation of health disorders from terminalia arjuna
- Process for producing enriched fractions of tetrahydroxycurcumin and tetrahydroxy-tetrahydroxy-curcumin from the extracts of curcuma longa

Australia

- Cysteine protease from ginger (zingiber) as a food improver and anti-inflammatory

China

- Medicaments and food for treatment or prevention of obesity and/or diabetes containing cicer arietinum extract

Cyprus

- Treatment and prevention of inflammation

Kenya

- Herbal compositions for treatment of diabetes

Spain

- Natural product in cream with anti-vitiligo therapeutic properties

South korea

- Nelumbinis semen extract for preventing and treating ischemic heart disease and pharmaceutical composition and health food containing the same

Bulgaria

- Therapeutical composition for the treatment of dermatosis comprising an extract of calendula officinalis and hypericum perforatum

Netherlands

- Functional berry composition

New Zealand

- A Composition

Denmark

- Method for altering the metabolism characteristic of food products

Annex - A

Description of Invention: Natural product based on vegetable ingredients with anti-vitiligo therapeutic properties to be employed in the white patches of depigmentation present in the skin with vitiligo and to regenerate the melanocyte, which is dysfunctional during the disease. It shows the following composition:

| |
|--|
| Watery extract of Pimienta racemosa 1:1 |
| Watery extract of Cucumis melo 1:2 100 ml. |
| Watery extract of Citrus aurantifolia 100 mg |
| Coenzyme Q-10 100 mg Pyridoxine Chlorhydrate |

TKDL Evidences: TKDL evidence established the use of *Cucumis melo* in the treatment of vitiligo/leucoderma since centuries.

Decision of EPO: EPO has set aside its intention to grant patent due to following reasons: "The application claims the usefulness of the combination of five constituents for the treatment of vitiligo, one of these constituents being a 1:2 watery extract of *Cucumis melo* containing catalase and superoxide dismutase. However, *Cucumis melo* has been known for its anti vitiligo property through local application in the Indian Systems of Medicine, since long, as is evident e.g. from Exhibits 1-5 (TKDL abstracts) as cited in the third party observation.

Hence, if one ingredient, here *Cucumis melo*, was already known for the treatment of vitiligo, then it had to be expected necessarily in an obvious manner that also a combination product comprising this known active ingredient must be effective for treating vitiligo.

Thus, as long as no surprising (superior) effect of the claimed combination product vis-à-vis the already known products comprising *Cucumis melo*, as described in the exhibits 1-5 and in D2, are shown by the applicant, inventive merits cannot be acknowledged."

Annex - B

Description of Invention: Use of a product obtained from a plant of *Pistacia* genus for manufacturing a medicament for treating or preventing cancer.

TKDL Evidences: TKDL evidence established the use of *Pistacia* species in the treatment of cancer since centuries.

Decision of EPO: EPO has set aside its intention to grant due to following:

"A third party observation has been filed on 24 June 2009 together with nine exhibits of TKDL abstracts. These exhibits seem to disclose the use of *Pistacia lentiscus* and *Pistacia vera* for the treatment of Cancer. The exhibits, in particular exhibit 7, appear pertinent to novelty and inventive step of the claims. The applicant is requested to take position. "

Annex - C

Description of Invention: Food composition being a mixture of grape juice and/or apple juice and berry juice, for use as a medicament for reducing the cardiovascular risk.

TKDL Evidences: TKDL evidence established the use of *Vitis vinifera* and *Malus pumila* for the treatment of cardio vascular diseases since centuries.

Current status: Applicant M/s Unilever NV, Netherlands after 5 years of filing its application has decided to withdraw its claims and application due to TKDL evidence.

Annex - D

Description of Invention: Applicant claimed the usefulness of *Nelumbinis semen* extract for preventing and treating ischemic heart disease.

TKDL Evidences: TKDL evidence established the use of *Nelumbinis semen* extract for the preventing and treating ischemic heart disease since centuries.

Decision of EPO: The applicant decided to withdraw his application.

Annex - E

Description of Invention: Applicant claimed the usefulness of an herbal composition comprising *Allium cepa* (Onion), *Zingiber officinale*, *Cuminum cyminum* and *Curcuma longa* as a slimming agent.

TKDL Evidences: TKDL evidence established the use of *Allium cepa* (Onion), *Zingiber officinale*, *Cuminum cyminum* and *Curcuma longa* for improving digestion process and as a slimming agent/fat destroyer since centuries.

Decision of EPO: The applicant decided to withdraw his application.

Annex - F

Description of Invention: Applicant claimed the usefulness of an herbal composition comprising *Cicer arietinum Linn* for treatment of obesity and non-insulin dependent diabetes.

TKDL Evidences: TKDL evidence established the use of *Cicer arietinum Linn* for treatment of obesity and diabetes since centuries.

Decision of EPO: The applicant decided to withdraw his application.

Annex - G

Description of Invention: Applicant claimed the usefulness of a plant extract from *Azadirachta indica*, *Aloe vera* and *Cinnamon* for the treatment of type II diabetes mellitus and its associated complications.

TKDL Evidences: TKDL evidence established the use of *Azadirachta indica*, *Aloe vera* and *Cinnamon* for the treatment of type II diabetes mellitus and its associated complications like diabetic furuncles since centuries.

Decision of EPO: The applicant decided to withdraw his application.

Annex - H

Description of Invention: Applicant claimed the usefulness of extract of *Aloe barbadensis Mill* for preventing and treating obesity.

TKDL Evidences: TKDL evidence established the use of *Aloe barbadensis Mill* for the treatment of obesity since centuries.

Decision of EPO: The applicant decided to withdraw his application.