

**TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (T.KD.L) -
UNDER THE UMBRELLA OF INTELLECTUAL PROPERTY RIGHT
(I.P.R)**

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ABSTRACT

The Traditional Knowledge Digital Library (TKDL) is a database tool to understand the codified knowledge existing for the Indian systems of medicine i.e., Ayurveda, Unani, Siddha, and Yoga as prior art. Its most important role is the prevention of misappropriation of Traditional Knowledge (TK). TKDL is a dynamic database, where formulations are continuously added, and it is continuously updated according to the inputs from the users of the database. Intellectual property (IP) is a term referring to a number of distinct types of expressions for which a set of rights are recognized under the corresponding fields of law. Ayurvedic compounds and formulations must be shelled and protected under the umbrella of IPR before they are introduced in the market. TKDL Access Agreement is unique in

nature and has in-built safeguards on Non-disclosure to protect India's interest against any possible misuse.

KEYWORDS: TKDL, Traditional Knowledge, Intellectual property rights, Ministry of AYUSH, Ayurveda, Biopiracy.

INTRODUCTION

The studies show that the global market for herbal drugs is lucrative, and trade is expected to reach USD 7 trillion by 2050.^[1] India with its traditional, holistic system of medicine-

Ayurveda has lots to offer to the world. The primary concern that the government faces is with the issues of piracy of the Traditional Knowledge (TK) and measures to implement this knowledge for uplifting the healthcare of the country.

To promote the Traditional Knowledge and increase its reach amongst the community and interdisciplinary sciences TKDL was launched. It is an Indian digital knowledge archive that contains traditional information, particularly regarding medicinal plants and preparations utilized in the Indian medical system.

The Traditional Knowledge Digital Library (TRDL) is a database with a tool to understand the codified knowledge existing for the Indian systems of medicine i.e., Ayurveda, Unani, Siddha, and Yoga as prior art. It was established in 2001 with the approval of Cabinet Committee of Economic Affairs (CCEA's) as collaboration between the Council of Scientific and Industrial Research (CSIR) under the Ministry of Science & Technology and the Ministry of AYUSH. However, TKDL contains the scanned images of medicinal formulations from the original books. TKDL covers over approx. two lakh formulations which have been taken from Ayurveda, Unani, Siddha and Yoga texts. It is pertinent to note that TKDL does not contain the entire information existing in the Indian Systems of Medicine. Rather than comprehensive, TKDL is a dynamic database, where formulations will be continuously added and continuously updated according to the inputs from the users of the database.^[2]

Intellectual Property Rights under World Intellectual Property Organization (WIPO) and Patents have attracted many individuals and organizations to explore possibilities of commercial benefits with Ayurvedic traditional knowledge. Although rules are not favoring to grant a patent on prior published knowledge, biopiracy managed grant of Patent on knowledge of Ayurvedic medicinal plants which has been successfully checked with references of data base of Traditional Knowledge Digital Library (TKDL). Current provisions of the Patent law of India are obstructive in nature for getting patent on Ayurvedic medicines. If we have to invite researchers from basic science to ensure quality, safety and efficacy of Ayurvedic medicines, there is an urgent need to amend laws of patent with pragmatic promotional policies. This will encourage more patents on numerous pharmaceutical, nutraceutical and cosmeceutical products based on Ayurveda. As every action of today's world is based on economic criteria, why stakeholders of Ayurveda should be deprived of it. New inventions would drive acceptance of Ayurveda as a global system of medicine.^[3]

Timeline of TKDL

- The TKDL journey began with Approach paper on setting up of TKDL in Oct 1999, submission of Approach paper to Standing Committee on Information Technology (SCIT), World Intellectual Property Organization (WIPO) in December 1999.
- Setting up of the interdisciplinary (inter-ministerial Task Force on TKDL) in January 2000.
- Submission of TKDL Task Force Report to Department of Indian System of Medicine and Homeopathy; and presenting TKDL Concept & Vision at International forum in May 2000.
- Cabinet Committee of Economic Affairs (CCEA's) approval for the TKDL Project in January 2001.
- Memorandum of Understanding (MoU) between Department of ISM&H now AYUSH) and National Institute of Science Communication (now CSIR-National Institute of Science Communication and Information Resources) in June 2001.
- Establishing TKDL team of Project Assistants (IT), Ayurveda, Patent Examiners, etc in October 2001 to March 2002.
- Presentation on Traditional Knowledge Resource Classification (TKRC) at International Patent Classification (IPC) Union for getting established WIPO-TK Task Force consisting of USPTO, EPO, JPO, China and India in February 2001.
- WIPO-TK Task Force recommended addition of a new subclass under A 61; Committee of Experts recommended: (i) inclusion of approx. 200 subgroups on TK against earlier few sub-groups on medicinal plants, (ii) linking of TKRC to IPC and (iii) continuation of work on biodiversity, TK and TCE (Traditional cultural expressions) in February 2002.
- First batch of data abstraction work on 36,000 Ayurveda formulations for creating TKDL in five languages, i.e., English, German, Spanish, French and Japanese in March 2003.
- Initiation of the TKDL Unani project & Initiation of TKDL Ayurveda Phase II in June & August 2004.
- Concordance between IPC and TKRC and approval on linking of TKRC with IPC in October 2004 Initiation of project on TKDL Siddha & Creating of TKRC containing approx. 25,000 subgroups in August 2005.
- Inclusion of 207 subgroups, related to algae, fungi, lichens or plants or derivatives thereof used in traditional herbal medicines in International Patent Classification, 8th Edition in January 2006.

- Approval on Access to TKDL database to international patent offices by Cabinet Committee on Economic Affairs in June 2006.
- Initiation of activities on creation of TKDL Yoga in January 2008.
- IPO Indian Patent Office in July 2009.
- TKDL Access Agreement with European Patent Office (EPO) in February 2009 TKDL Access Agreement with USPTO in July 2009.
- The first prior art evidence based on TKDL citations under Third Party observations against 35 patent applications submitted to EPO leading to development of a formalized structure for filing Third Party Objections (TPOs)/oppositions at various international patent offices in July 2009.
- TKDL Access Agreement with German Patent and Trademark Office (DPMA) in October 2009 TKDL Access Agreement with United Kingdom Intellectual Property Office & TKDL Access Agreement with Canadian Intellectual Property Office (CIPO) in February 2010.
- TKDL Access Agreement with Intellectual Property Australia (IP Australia) in January 2011 TKDL Access Agreement with Japan Patent Office (JPO) in April 2011.
- First Amending Agreement to TKDL Access Agreement. with European Patent Office (EPO) in July 2012.
- First Amending Agreement to TKDL Access Agreement with Canadian Intellectual Property Office (CIPO) in August 2012.
- First Amending Agreement to TKDL Access Agreement with United Kingdom Intellectual Property Office (IPO) in January 2014 TKDL Access Agreement with Chile Patent Office (INAPI) in May 2014.
- First Amending Agreement to TKDL Access Agreement with Japan Patent Office (JPO) in June 2014 TKDL Access Agreement with Intellectual Property Corporation of Malaysia (MyIPO) in October 2015 TKDL Access Agreement with Ros patent (Russia) in June 2017.
- TKDL Access Agreement with INDECOPI (Peru) in June 2017.
- First Amending Agreement to TKDL Access Agreement with Chile Patent Office (INAPI) in October 2017.^[4]

TKDL Contents-: The information on traditional medicines appears in a standard format in TKDL. For example, formulations on Indian Systems of Medicine appear in the form of a text, which comprises the following main components.

- **Name of the Formulation**

Knowledge since known.

Composition of the formulation with their parts used and their quantity.

- **Method of preparation of the formulation**

Dose of the medicine

Adjuvant/ Vehicle of medicine

Mode of Administration of the formulation

Time & duration of Medication

Action of the formulation

Therapeutic usage of the formulation

Contraindications

Bibliographic details

Scanned Prior-art.

Objectives of TKDL:- The TKDL's goal is to safeguard the nation's traditional knowledge by electronically documenting it and categorizing it in accordance with worldwide patent classification standards to prevent it from being exploited through biopiracy and unethical patents. The TKDL aims at the creation of databases for further research and development. It aims at breaking format and language barriers. The most important aim is the prevention of misappropriation of Traditional Knowledge (TK). It intends to act as a bridge between information recorded in ancient Sanskrit and patent examiners (with its database containing information in a language and format understandable to patent examiners).

INTELLECTUAL PROPERTY RIGHT AND TKDL

The term Intellectual property is defined in the WIPO convention to include rights relating to, literary, artistic and scientific works, performances of performing artists, sound recordings, and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and, all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic field.^[5] The course of evolution of these legal principles governing intellectual property rights had over centuries as this was not used until the 19th century. The use of the term intellectual property began not until the late 20th century.^[6]

Intellectual property (IP) is a term referring to a number of distinct types of expressions for which a set of rights are recognized under the corresponding fields of law. Common types of intellectual property rights include copyrights, trademarks, patents, industrial design rights, and trade secrets in some jurisdictions. Laws and concepts behind copyright and patents are not new. Ayurvedic compounds and formulations must be shelled and protected under the umbrella of IPR before they are introduced in the market. The Indian Patent Office has received numerous applications from Indian as well as foreign investors and pharmaceutical companies seeking patents in all fields of technologies and Ayurvedic medicines, which can be easily seen published on the website of the Patent Office.^[7]

IPR for Ayurvedic drugs: There are two types of Ayurvedic medicines prepared in the country. First the classical drugs second are the patent and proprietary medicine manufactured by the pharmaceutical industry of the Indian Systems of Medicine on their own developed formulations. Since these crude drugs raw material may not have been evaluated scientifically on botanical, pharmacognostical, chemical and pharmacological parameters it is therefore necessary to screen them out for various ailments. Pharmaceutical industry of ISM in the country is very large and manufacturing its drugs on the basis of license issued by the Drug control authorities of the respective states. Their trade history, supply, demand involvement of national level institutions and their trade market is not properly established. Looking into all these aspects it is necessary that the aspects of IPR and assessment of raw material used in ISM is given top priority. The forum of parliaments on IPR must be executed.^[8] The agreement on Trade-Related Aspects of IPR as contained in the final act of the Uruguay Round, seeks to strengthen intellectual property protection in order to promote world trade and rapid economic development.^[9]

Accession to TKDL

At present, as per the approval of Cabinet Committee on Economic Affairs, access of TKDL is available to fifteen Patent Offices (European Patent Office, United State Patent & Trademark Office, Japan Patent Office, United Kingdom Patent Office, Canadian Intellectual Property Office, German Patent Office, Intellectual Property Australia, Indian Patent Office, Chile Patent Office, Intellectual Property Corporation of Malaysia, Ros patent- Intellectual Property Office of Russia, Peru Patent Office, Spanish Patent and Trademark Office, Danish Patent and Trademark office and National Industrial Property Institute, France), under TKDL Access (Non-disclosure) Agreement. As per the terms and conditions of the Access

agreement, examiners of patent office can utilize TKDL for search and examination purposes only and cannot reveal the contents of TKDL to any third party unless it is necessary for the purpose of citation. TKDL Access Agreement is unique in nature and has in-built safeguards on Non-disclosure to protect India's interest against any possible misuse.

IMPACT OF TKDL

In addition, pre-grant oppositions are being filed at various International Patent Offices, along with prior art evidences from TKDL. Significant impact has already been realized. So far more than 271 patent applications have either been set aside/ withdrawn/ amended, based on the prior art evidences present in the TKDL database without any cost and in few weeks/months of time, whereas APEDA had to spend about seven crores towards legal fee only for getting few claims of Basmati rice patent revoked.

DISCUSSION AND CONCLUSION

TKDL is proving to be an effective deterrent against bio-piracy and has been recognized internationally as a unique effort. TKDL has set a benchmark in TK protection around the world, particularly in TK-rich countries, by demonstrating the advantages of proactive action and the power of strong deterrence. The key here is preventing the grant of wrong patents by ensuring access to TK related prior art for patent examiners without restricting the use of traditional knowledge.

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