

Traditional Knowledge Digital Library as Patent System Facilitator

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Abstract: The concept of the Traditional Knowledge Digital Library (TKDL) first emerged in India two decades ago. It upholds the current Indian patent law, which forbids the filing of patents based on traditional knowledge that is already in the public domain. Although, TKDL has been quite helpful in preserving traditional knowledge, it can be improved to maximize its potential. With tech advancements, it's necessary to ensure that traditional knowledge is secured to facilitate the Intellectual Property regime, and prevent the exploitation of local customary knowledge. The primary issue concerning the current operational model is financial in nature. Many advocates strongly contend that access to the TKDL should be facilitated through commercialization. It is essential to grant access to the database to third parties to enhance awareness and promote indigenous knowledge systems. Allowing third-party access is therefore significantly beneficial from a financial perspective. In this regard, we have proposed the establishment of a TKDL fund, aimed at supporting various indigenous communities. This fund would generate financial returns from granting access, which would be distributed among indigenous communities and subsequently utilized for their development, thereby acknowledging their contributions in the realm of traditional knowledge.

Keywords: traditional knowledge; traditional knowledge digital library; patent; prior art; indigenous communities

Citation: Alok Kumar Yadav, Vibha.

2024. Traditional Knowledge Digital Library as Patent System Facilitator. *Trends in Intellectual Property Research* 1, 21-25. <https://doi.org/10.69971/tipr.2.1.2024.20>



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1. Introduction

India is one of the mega-diverse countries of the world, harboring nearly seven to eight percent of the recorded species of the world, and representing 4 of the 34 globally identified biodiversity hotspots and it is also a vast repository of traditional knowledge associated with biological resources.¹ "Traditional knowledge refers to the immense knowledge possessed by indigenous people which has been developed from long and continuing customs and practices of indigenous or local communities (Bhandari, 2019)." Biodiversity is extremely relevant to health. Majority of Indians depend for their health care needs upon folk and classical remedies based largely on plants, other biological materials, minerals and related traditional knowledge (Dutfield, 2004).

The indigenous communities of India have utilized their traditional knowledge of plants and herbs as local remedies to treat the novel coronavirus (Ola, 2022). For instance, to maintain immunity during the COVID-19 outbreak, the Ministry of Ayurveda, Yoga, & Naturopathy, Unani, Siddha & Sowa-rigpa, and Homoeopathy (AYUSH) had advised consuming "kadha," a traditional ayurvedic and medicinal drink from India.^{2,3} It is a natural treatment that treats symptoms like a fever, cough, and the common cold and it improves digestion and related problems.⁴ Its antioxidant, antiseptic, and other nutrients help to boost immunity.⁵

The exploitation of traditional knowledge by biopiracy is rising globally. Bio piracy refers to the use of intellectual property (IP) regime to establish exclusive ownership and control over biological resources, biological products, and biological processes that have been employed for many years in non-industrialized civilizations (Nadkarni & Rajam, 2016). This abuse of the traditional

¹ Available online: <https://www.cbd.int/countries/profile/?country=in> (accessed on 15 October 2024)

² Available online: <https://ayushnext.ayush.gov.in/detail/post/kadha-drops-the-ayurvedic-wonder-for-covid-19-immunity-recommended-by-doctors> (accessed on 15 October 2024)

³ Ibid.

⁴ Ibid.

⁵ Ibid.

knowledge, for commercial purposes⁶ is a threat to the communities who are actual holders of traditional knowledge. Traditional knowledge can be transformed into wealth by the way of IP regime.⁷ The creation of intellectual property needs investment of time, money and other efforts. But traditional knowledge makes the invention and patenting easy as it saves the time, money and other efforts of the individuals and firm in research and development.⁸

India has taken many steps to protect its traditional knowledge from being exploited, including through the Biological Diversity Act of 2002, the Protection of Plant Varieties and Farmers Rights Act of 2001, and the Patents (Amendment) Act of 2005. A key initiative that forbids the issue of patents based on ancient and precious Indian traditional knowledge, protecting traditional knowledge and the interests of indigenous communities is by traditional knowledge digital library (TKDL). It is India's defensive protection of traditional knowledge through the development of digital database as TKDL which initiated in 2001 (Krishna, 2019). The extensive database of TKDL is a prime initiative to prevent misappropriation of the traditional knowledge and it is very beneficial for researchers, enterprises, and indigenous community.^{9,10}

The TKDL initiative aims to address various challenges that currently affect the traditional knowledge systems of indigenous communities. The unavoidable intersection of traditional knowledge with the Intellectual Property Rights (IPR) framework has frequently led to the degradation of natural resources and, regrettably, the exploitation of these communities. This exploitation has fostered a widespread skepticism towards commercialization, as it is often perceived that commercialization inherently leads to commercial exploitation. In this context, the achievements of TKDL are highlighted, while its shortcomings serve merely as motivation for enhancement. Current research explores the current potential of traditional knowledge digital library suggesting improvements in it. The structure of the traditional knowledge digital library and how it supports Indian patent law are described. Along with the advantages, there are negatives as well, which will be examined in more detail. Finally, suggestions and recommendations have been discussed to overcome those drawbacks.

2. TKDL and the Patent Law in India

The Patent Act of India, 1970 has many provisions which are significant concerning the patent applications identified with traditional knowledge. Section 3 of the Patent Act provides the circumstances which are not inventions under the said Act, 1970. It includes total 16 situations in which a patent cannot be granted.

Section 3(p) says that the duplication of conventional knowledge is not patentable. Section 3(e) says that a substance acquired by a simple admixture coming about just in the accumulation of the properties of the segments thereof isn't patentable. Section 3(b), (c), (d), (f), (h), and (j) are significant for the patent applications identified with customary knowledge. Section 25(1)(k) provides that, where the application has the invention, inasmuch as stated in any claim of the complete specification, is anticipated in light of any local or indigenous group in India or elsewhere that has access to information that is either oral or otherwise, then the opposition may be filed to Controller against the grant of patent. This opposition may be filed by any person under Form 7(A) where an application for a patent has been published but a patent has not been granted. There is no specified time limit for filing but 6 months of publication are preferable for it.¹¹ Section 25(2)(k) provides that the opposition may be filed to the Controller against the grant of patent where the invention is anticipated in light of any local or indigenous community in India or elsewhere that has access to information that is either oral or otherwise, as described in any claim of the complete specification. The opposition may be filed by any person who is interested in the invention under Form 7 at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent.¹²

Further, government of India has issued the guidelines which need to be followed by the patent examiners and controllers while examining the patent applications. These guidelines indicate the process in which a TK may be identified and thereafter opposition is filed by them so that, the application may be amended or withdrawn or refused. The guidelines are as follows¹³:

1. It ought to be guaranteed that all patent applications identified with TK are accurately distinguished, screened and classified as traditional knowledge. The concerned in charge is responsible for the screening and for appropriate Patent Cooperation Treaty Classification to ensure that the TK may be routed to right group for examination. Only the technical head has the authority to rescreen or reclassify an application if it was incorrectly designated as TK in a rare instance.
2. In the concerned group, the group leader will himself go about as the controller for all applications identified with TK. The group leader or controller ensures that TK is confirmed completely and choose one appropriate for managing all applications regarding TK. In each case identified with TK, the examiner will complete an intensive search for expectation in TKDL or potentially different information available. The Patents Act, 1970 warrants that the subject claimed in a patent application should be novel. The inventive step is another standard of patentability. Usually, it is supposed to be the last guardian of the patent framework.

⁶ Ibid.

⁷ Available online: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf (accessed on 15 October 2024)

⁸ Ibid.

⁹ Available online: https://www.researchgate.net/publication/41043855_Protecting_Traditional_Knowledge_Digitally_a_Case_Study_of_TKDL (accessed on 15 October 2024)

¹⁰ Ibid.

¹¹ The Patent Rules, 2003, Rule 55.

¹² The Patent Rules, 2003, Rule 55A.

¹³ Available online: https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf (accessed on 15 October 2024)

3. The National Biodiversity Authority's approval should be sought for any bio resource obtained from India and used in a development for which a patent application has been filed, and controllers or examiners are tasked with ensuring strict compliance with the aforementioned request.
4. On the official website of Controller General of Patents Designs and Trademarks, India, the system administrator must post a separate link listing all ongoing patent applications for TK that are published in accordance with section 11(A) of the Patents Act. According to the screening field in the module, this list should be automatically updated on the website in real time. The list should at least include the following fields: application number, filing date, invention title, and applicant name. The list of patents granted on applications identified with TK ought to likewise be published on the site for every such patent allowed from first July 2012. It must contain the application number, patent number and other relevant information.
5. TKDL is a database created by the Council of Scientific and Industrial Research (CSIR) and AYUSH Ministry to save the information possessed by the indigenous communities of India.¹⁴ TKDL contains more than 4.2400,000 recipes from the writings of customary medication frameworks of India including Ayurveda, Unani and Siddha.¹⁵ The defensive protection through TKDL has been effective in safeguarding Indian traditional knowledge from misappropriation and is considered a global benchmark. A total of 418885 formulations including 119269 in Ayurveda, 236399 in Unani, 54689 in Siddha, 4151 in Yoga and 4377 in Sowa Rigpa have been transcribed so far into the TKDL database (data as on March 25, 2022).¹⁶ The total numbers of books or texts by the Indian traditional system of medicine that are currently available in the TKDL database are 281.¹⁷ TKDL is accessible in 5 languages which are English, German, French, Japanese, and Spanish and is based on innovative classification system that known as traditional knowledge resource classification (TKRC).¹⁸ TKRC incorporates around 5000 sub-groups pertaining to restorative plants and this data is organized under segment, class, subclass, gathering and subgroup as indicated by the International Patent Classification (Abha Nadkarni & Shardha Rajam, 2016). Internationally, TKDL is accessible to fifteen patent offices by the way of TKDL Access (Non-disclosure) Agreement.¹⁹

A considerable influence has already been felt. As of now, more than 271 patent applications have either been dismissed, withdrawn, or amended based on prior art evidence found in the TKDL database without incurring any fees and in a matter of weeks or months.²⁰ TKDL has received recognition on a global scale for its innovative approach and is shown to be an effective deterrence against bio-piracy.²¹ Currently TKDL consists 34 million pages in a patent application format on 270 thousand medicinal formations.²² TKDL has established a standard for TK protection around the world, particularly in TK rich countries.²³ It is important to ensure that patent examiners have access to prior art that is relevant to conventional knowledge without constraining their ability to use it.²⁴

TKDL has helped to protect the traditional knowledge of India by proving a digital database.²⁵ In 2016, a patent application '*Use of Cannabinoids in the Treatment of Inflammatory Skin Diseases*' was filed by M/S GW Pharma Limited/ Great Britain in European patent office. The examiner's report indicated that, invention doesn't involve inventive step as the proposed solution is the use of cannabinoidic acid (cannabis). It is already known as proved by the TKDL. Accordingly the claims were amended in 2020.²⁶ In 2013, a patent application '*Herbal Preparation*' was filed by M/S Perminov, Roman in Australia. The examiner's report provided that, the claims are not novel and lack inventive step. In fact the claimed mixture of white radish juice and onion juice is suitable for treatment of burns which is TK registered with TKDL. Following the objections, the application was amended in 2018.²⁷ In 2010, a patent application '*Anti-Adipogenic compositions containing piper betel and dolichos bifloras*' was filed by Laila Nutraceuticals in Controller General of Patents Designs and Trademarks, India. When the evidence was produced with the help of TKDL, the application was refused in 2021.²⁸ TKDL halts incidents of bio piracy in this way.

3. Deficiencies in TKDL

Although TKDL is a revolutionary initiative, it has certain inadequacies, which are reducing its effectiveness. In the current framework of the Traditional Knowledge Digital Library (TKDL), the sharing of traditional knowledge information occurs solely between the Council of Scientific and Industrial Research (CSIR) and the Intellectual Property Office (IPO), with which a non-

¹⁴ Available online: <https://www.tkdil.res.in/tkdil/langdefault/Common/SourceInfo.asp?GL=Eng> (accessed on 15 October 2024)

¹⁵ Ibid.

¹⁶ Available online: <https://pib.gov.in/PressReleasePage.aspx?PRID=1809661> (accessed on 15 October 2024)

¹⁷ Supra note 19.

¹⁸ Available online: <https://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdil.asp?GL=Eng> (accessed on 15 October 2024)

¹⁹ Ibid.

²⁰ Available online: <https://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdil.asp?GL=Eng> (accessed on 15 October 2024)

²¹ Ibid.

²² United Nations Environment Programme [UNEP], Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, ¶40, UNEP/CBD/WG8J/8/INF/5 (October 7, 2013).

²³ Ibid.

²⁴ Ibid.

²⁵ Available online: <https://www.tkdil.res.in/tkdil/langdefault/Common/outcomemain.asp?GL=Eng> (accessed on 15 October 2024)

²⁶ Available online: <https://www.tkdil.res.in/tkdil/langdefault/Common/Outcome.asp?PatentOffice=EPO> (accessed on 15 October 2024)

²⁷ Available online: <https://www.tkdil.res.in/tkdil/langdefault/Common/Outcome.asp?PatentOffice=AIPO> (accessed on 15 October 2024)

²⁸ Available online: <http://www.tkdil.res.in/tkdil/langdefault/Common/Outcome.asp?PatentOffice=CGPDTM> (accessed on 15 October 2024)

disclosure agreement is established.²⁹ Non-disclosure agreements are typically characterized by their secretive and confidential nature, as they are designed to ensure that only the parties involved are privy to the subject matter. Disclosing this information to third parties could potentially compromise the interests of those parties or conflict with the broader public interest (Kiernan, 1994).

TKDL offers the International Patent Offices (IPO), a database for prior art search in an effort to combat bio piracy. One of the major procedural drawbacks of TKDL is that, the decision to award a patent, rests with the patent examiner's discretion and competence and this is due to the fact that what one patent examiner may identify as prior art may not be accepted by another (Sharma, 2017).

TKDL does not examine the specific context or language that was used for this purpose in depth; it merely documents the information (Krishna, 2019). It's challenging, since the information was not available in TKDL and patents were awarded on it. For example, the Aloe Vera case in which a patent was issued only because the novel concept in the application was chlorinated water rather than pure water, which the patent examiners had not discovered during examination of application.³⁰ Since the documents in TKDL system are not given in detail; it affects the efficiency of TKDL.

The TKDL database can only be viewed by the IPO that has signed a non-disclosure agreement with CSIR because the TKDL is a closed-access model.³¹ Due to security precautions, it is not disclosed.³² Being unavailable to the wider community clashes with the patent law, which mandates prior art searches before filing an application to determine if an invention is patentable or not. Even researchers who want to sign the benefit-sharing agreements based on codified formulations are prevented from accessing it.³³ It hurts the commercial interests of indigenous communities besides hindering Indian TK's development and commercialization.

Another issue is that the scope of oral knowledge or inaccessible knowledge that is available in indigenous societies is excluded (Fredriksson, 2022). TK is a part of everyday life and cannot be contained in written forms; it also contains a great deal of oral information and undocumented, unknown, or undeclared information.³⁴ Additionally, the TKDL only contains a small subset of traditional knowledge and excludes knowledge related to agriculture, conservation, and other fields (Sharma, 2017)

One major problem is that "prior art" is not universally understood in the legal community.³⁵ For instance, the USPTO does not recognize the information provided by TKDL as prior art. This renders TKDL useless in USPTO.³⁶ Even within a single legal system, there are variations through which patent examiners generally accept as previous art.

The perception of restricted access for third parties as another deficiency within the TKDL framework can be understood through a financial lens, particularly regarding the necessity of consideration for a valid agreement. When the Council of Scientific and Industrial Research (CSIR) establishes agreements with patent offices, the role of these offices in safeguarding Indian traditional knowledge from unauthorized use is regarded as part of the 'consideration' within the agreement. Given that CSIR has invested a substantial amount of taxpayer funds into the TKDL initiative, this consideration does not adequately reflect the project's financial worth.

The other main problem which is being suffered by traditional knowledge is the recognition of this as a component of the public domain allows individuals to freely access and claim rights over it for their personal use (R.A. Mashelkar, 2024). The current TKDL framework has been subject to criticism on three primary grounds. First, it limits access for third parties by establishing non-disclosure agreements exclusively with patent offices for the sake of protection. Second, there is a lack of financial compensation for indigenous communities, who are recognized as the rightful beneficiaries of the TKDL framework, as outlined in "Article 29 of the Constitution of India and the Scheduled Tribes and Other Forest Dwellers (Recognition of Forest Rights) Act, 2006." Finally, the traditional knowledge contained within the TKDL is perceived as belonging to the public domain, rather than being openly accessible or available to the public.

To improve effectiveness, it is crucial to establish a uniform interpretation of the term "prior art" across different legal frameworks. Regarding credibility, it is essential to acknowledge the copyright associated with the digitized data within TKDL. The royalties generated for those who initially compiled or translated the traditional knowledge will support further research in this area. This approach will not only bolster the legitimacy of TKDL but also encourage additional exploration of traditional knowledge. In terms of procedural issues, enhancing the expertise of patent examiners is necessary, extending beyond just patents related to traditional knowledge. Specific recommendations include ensuring that the documentation for TKDL is conducted with the highest level of diligence to prevent confusion arising from inadequate translations. Additionally, applicants should bear the responsibility of disclosing the geographical origin of the information that informed their inventions. A further procedural recommendation is that the compensation of patent examiners should not be tied to the volume of applications processed; they should be held accountable for any patents granted without due diligence. Lastly, it is imperative to maintain accurate records of cases where patent applications have been significantly influenced by interventions based on information sourced from TKDL.

4. Conclusions

²⁹ Available online: <http://www.tkdil.res.in/tkdil/Langdefault/common/BioPiracy.asp?GL=> (accessed on 15 October 2024) (“The translated version of all the TKRC codes is ported in the database. The abstraction is done by the subject experts. The codes once saved in meta data directory are converted in different languages based on Unicode technology”).

³⁰ Ibid.

³¹ Ibid.

³² Ibid.

³³ Ibid.

³⁴ Ibid.

³⁵ Ibid.

³⁶ Id.

TKDL is great helper against bio piracy which attempts for IP protection to information that is already in the public domain. This is contrary to the spirit of IPRs as IP protection is only granted to inventions that involve an inventive step. Despite lot of efforts and time put in TKDL, its inadequacies are apparent now. Today, TKDL has emerged as a source of support for numerous countries striving to safeguard their traditional knowledge by promoting it and raising awareness on a global scale. Further, a proactive defense is required to safeguard the TK. It might be included into TKDL system or it might be developed as a separate system. Positive protection would strengthen the protection system, dissuade applicants from applying for patents, and encourage them to do so more cautiously. To effectively safeguard traditional knowledge, it is preferable to either exclude it from the public domain or impose specific conditions on its use within that domain. However, both alternatives raise a significant dilemma concerning the interpretation of public domain, which lacks a universally accepted definition. Rather, it is characterized by multiple interpretations within the framework of Intellectual Property Law.

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