Journal of Intellectual Property Rights
Vol 29, March 2024, pp 133-140
DOI: 10.56042/jipr.v29i1.3373

Impact of TKDL on Patent Applications in the Field of Bio-resources and the Associated TK

Pankaj Kumar[1†] and Ameeta Sharma[2]

[1]National Law University and Judicial Academy, Guwahati — 781 031, India

[2]Department of Biotechnology, IIS (deemed to be university), Jaipur — 302 020, India

Received: 28th June 2023; revised: 17th January 2024

After the incidents of bio-piracy and bio-patenting of Indian bio-resources and the associated traditional knowledge, India has successfully initiated an institutional mechanism named Traditional Knowledge Digital Library (TKDL). Such Traditional Knowledge (TK) databases help to establish prior-art and therefore disprove patentability, protect the county's TK from wrong patenting. As being codified in such a way, the database enables timely and economically establishing non-patentability of inventions based on biological TK. India as a country has become the first in the world to have such a tool. TKDL is an open prior art model to keep a check against bio-piracy. Here in this work, India's TKDL impacts on patent applications in the field of traditional knowledge associated with bio-resources have been evaluated. TKDL has around 34 million pages that include 2.90 million compositions of the diverse medicine system of India. Thepaper discloses various remarkable particulars associated to bio-piracy, bio-prospecting, and how TKDL is acting as a protecting shield against them, thus showing effectiveness of the TKDL with the help of discussed case studies.

Keywords: Bio-Piracy, Bio-Resources, Patent Revocation, Traditional Knowledge Digital Library, Traditional Knowledge

Bio-prospecting, Bio-piracy and Patent issues in the field of bio-traditional knowledge have always been a topic of interest for the researchers. Traditional knowledge, including traditional medicinal information, proved its immense value and hence bio-prospecting is attracting researchers indulged in developing goods based on such knowledge and commercializing products based on such knowledge.[1] It is noted that in the healthcare sector, more than 70% of the population depends on medicine based on traditional knowledge. Unfortunately, such great resources have been unfairly appropriated by means of bio-piracy and bio-patenting. As a result, without the prior consent of the concern, the society maintains such TK since time immemorial, not sharing with them the profits out of such commercialization.[2]

In response to up-risen apprehension of bio-piracy, the concerned authority in India has translated ancient manuscripts in the electronic form. The TKDL project was initiated in the year 2001 as a sequel to the conflicts fought by India against the patents granted or approved by the United States Patent & Trademark Office (USPTO) for Basmati Rice and Turmeric and the for Neem (*Azadirachtaindica* L.) patent grant by the European Patent Office (EPO), so that there would exist proper documentation of its affluent TK.

In view of numerous cases of bio-piracy and more particularly patenting of bio-diversity and the associated traditional knowledge, India took the initiative and developed a database named Traditional Knowledge Digital Library, a mutual project between the CSIR, and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH).

Significance of TKDL

TKDL prevents the grant of patents to inventions which are either TK, or based on the same. It seeks to act as a bridge between new science and TK, and can be used for catalyzing higher research and innovations. Many applications pending in various other patent offices have also been challenged as done successfully in the USA earlier in case of turmeric. Such an incorrect granted patent later requires huge efforts, time and funds to revoke.TK includes both the documented as well as undocumented concerned knowledge available. TK which is part of the public domain is an easily accessible resource and is being continuously exploited for bio-prospecting. TK, as being part of public domain does not mean that the concerned communities have given up their claims over it. However, there are abundant cases of

†Corresponding author: Email: ipr.pkumar@gmail.com

misappropriate use of TK like bio-piracy which have been reported. In view of huge bio-prospecting, many cases of bio-piracy reported earlier, included patenting of inventions based on TK by the applicants which were not having any prior consent of the concerned TK society. Generally, no as such any profit share arrangement was existing with the TK society, thus there lacked a policy for any contractual obligations.[3] Once a person gets a patent based on such TK based inventions, but later he/she may have problems to commercialize such traditional products by the concerned societies having no such IPRs therein and may be prosecuted on the ground of infringement of other IPRs therein.[4]

In the present age of information and knowledge management, the access of information is not restricted locally and in fact they are well disseminated in print documents and as well online across the border. 'Novelty' is one of the essential criteria for patent and due to lack of accessible codified database with such examiners, sometimes patents are wrongly granted by the examiner to the application for inventions based on such TK. By just knowing the age-old formulae of curing diseases and much other useful knowledge, which is known even by the common public in India, there are cases where the poachers have patented these as their own inventions. Many times, such inventions passed the test of patentability in-spite of having the knowledge which is either a part of public domain or inspired from such knowledge and may be seems obvious. Some of these wrongly granted patents were opposed post-grant by different Indian entities as being 'person interested'.

Some of such bio-piracy cases where the source of the bio-resources and the associated traditional knowledge are from India, which includes US Pat No. 5,401,5041 for the wound-healing properties of turmeric which was successfully revoked in 1997 by CSIR in India;[5] European PatNo. 436257 for an anti-fungal product from the Neemgranted to W.R. Grace Company and US Department of Agriculture which was successfully revoked;[6] US Pat No. 5,663,484 on Basmati rice lines and grains to Ricetec Company from Texas (US) where the Agricultural and Processed Food Products Export Development Authority (APEDA) from India filed a request for re-examination for such grant and consequently the specific claims were withdrawn.[7]

Protection of Traditional Knowledge

The indigenous communities do not have the adequate awareness or fund safeguarding their TK. A policy in the subject is needed to promote its sustainable utilization and sufficient IP protection with justified benefit sharing is also required.So, there is need of an accessible database of traditional knowledge for the following reasons:

Public Awareness

Such information exists in local languages and as being the language barrier, it hardly enables others to use it as they remain unaware about such precious information.[8]

Researchand Development

It is needed to codify the TK which can be further utilized to develop new medicine and other goods for public welfare.

Recognition of the Concern Local Society

Generally indigenous peoples do not have adequate awareness regarding the IPR system and further the fund to patent such knowledge of them is also an issue. In addition to the absence of a strong policy here, commercial entities are free to do so when they find such information commercially viable. It is noted that extraction techniques and applications of the plant part(s) based on such knowledge, are applied for patent frequently, and also sometimes they are issued patents for it.[9] Generally, no benefit sharing mechanism in such matters exists and so it could be considered immoral rather than illegal. It is very unfortunate, when someone interested in such existing resources, doing its commercialization without having given any prior information and taking consent or sharing in the profit with those maintaining it since time immemorial. Height of such misappropriation happens when such a person/organization also tries to monopolize it by patenting as their own creation or property.

Protection

The appropriation of such knowledge of indigenous people for the commercial use, without their any prior consent or even sharing in the profits is one of the major concerns internationally today. This seeks some sort of action to be sought, thus to protect such TK through national and international frameworks.[10]

Prior-art Documentation

One of the reasons for such incorrect patenting in this particular subject matter is the inadequate documentation availability and its accessibility to the examiner to search it as a prior art. Traditional knowledge, particularly the medicinal TK, exists in

local languages and is not accessible at the international patent offices.[11] Consequently, the patent examiners wrongly grant patents to inventions submitted based on associated knowledge on the bio-resources. Lacking codification, many applications based on traditional knowledge are wrongly granted. In view of numerous bio-piracy cases and erroneous grants of patents to traditional knowledge, it is needed to have some sort of accessible tool having codification of such knowledge establishing prior-art.

Patentability Establishment

The patent examiners, while examining patentability of the application, use available resources for patent and non-patent literature. Codification of TK in the official languages certainly helps the patent office to examine its patentability particularly the criteria of novelty and inventiveness. In view of numerous wrong patents granted on the subject of biological TK, it seems that these resources get misappropriated in both the International and National Patent System due to lack of access to such knowledge by the Examiners.

Easy to Oppose Economically and Efficiently

Some of such patent revocations are extremely time-consuming, expensive and burdensome. Opposition to such application or revocation of such a patent is not so easy and needs huge efforts and funds. In view of the huge costs and time, revocation of such patents, seems not to be a viable option.

Hence, traditional knowledge rich countries like India need to develop database of their TK to ensure that no incorrect grant of patent is there, owing to not having access to such prior art at the end of Patent examiners.The incidents of bio-piracy lead to cooperative efforts of CSIR and additional associations to thwart incorrect patenting in the TK, finally establishing a TKDL in India.[12]

Traditional Knowledge Digital Library is an online database which contains translations of manuscripts and textbooks in many languages like Spanish, English, French, German and Japanese. Such a TK database certainly would be the milestones in the path of preserving national TK.[13] The TKDL was set up in 2001 as a repository of 1200 formulations of various systems of Indian medicine including Ayurveda, Unani and Siddha. It is a record that contains 34 million pages on some 2,260,000 traditional medicinal formulations in multiple languages.[14] The information has been recorded from various languages including Sanskrit, Urdu, Persian, and Arabic. It provides information on TK of India, in languages understandable by the examiners at International Patent Office.[15] It operates as a link between Patent Examiners and the information of traditional knowledge present in local languages.[16]

TKDL has surmounted the language and configuration difficulty of the contents by its precise converting and structuring biological medicinal formulations of traditional Indian Systems with the assistance of tools of information technology and an established classification system - Traditional Knowledge Resource Classification (TKRC).The TKDL can help the Patent Examiners to examine the patentability of inventionsin a better mode and also prohibit the wrong grant of patent on such inventions. The Government of India also initiated agreements with various patent offices worldwide including EPO, USPTO, Japan Patent Office (JPO), etc. for access to its Traditional Knowledge Digital Library.TKDLis not accessible to the general public and only accessible to patent offices, which are having the access agreement along with term of non-disclosure to safeguard TK of India. As per the agreement, the examiners are using it as a tool for prior-art search and its contents may only be open and accessible to the applicant for the purposes of reference in the examination reports.

TKDL helps in establishing non-patentability of such TK which lacks ‘novelty’ and ‘non-obviousness’ and therefore assist Patent Examiners to conduct prior art searches proficiently and is a very effective means of preventing incorrect grant of patents. As all the information on this database will qualify as prior art and will thereby prevent incorrect patents from being granted. It is enormously achieving the goal to protect the indigenous knowledge of India from being patented as numerous applications for patent and granted patents have been successfully objected, opposed, invalidated and revoked numerous patent applications, some of them at pre-grant and others at post-grant patent.

Structure of TKDL

TKDL input goes further by framing a Traditional Knowledge Resource Classification which had been accepted by WIPO International Patent Classification (IPC). It is an ordered classification and theideabehind is establishment of systematic arrangement and proper retrieval system for TK of medicinal plants and is being structured under sections like-class, sub-class, groups and sub-group in accord with the IPC for the ease of its employment by the international patent examiners. It has about 5,000 sub-groups besidesonly some

subgroups are existing in IPC.[17] The information encompass in gregarding two lakh formulations have been transcribed intended for realizing the purpose of TKDL Project.[18]

The Slokas translated and arranged into an ordered language under TKRC experts in subjects including Ayurveda, Unani, Siddha and Yoga. The codes from Slokashave been filled into data entry screen and saved in the database. The codes saved in meta data directory are converted in English, German, French, Japanese and Spanish languages based on Unicode technology.[19] The TKDL software further moretranslate traditional/ conventional terminology into contemporary vocabulary, for instance, "Jwar to fever", "Turmeric to *Curcuma longa*", "Mussorika to small pox" and so on.[18, 20]

TKDL for investigation includes a search interface in multiple languages which offer acomplete text hunt and recoveryor retrieval of TK related information on keywords and IPC. The search components include one or numerous word searches, complex Boolean expression search, Field search, Proximity search, Phrase search, TKRC codes search, IPC search and many more in the form of advance and uncomplicated search alternatives. Advance search allows the client, search by means of Boolean expressions, with the terminology like "near", "and not" and "and". TKRC comprises of approximately 27,000 sub-groups meant for Ayurveda, Siddha, Yoga andUnani, like the IPC. It has integrated around 200 sub-groups categorized under A61K 36/00 in IPC, thus improving the worth of prior-art search.[21]IPC Union steered to the formation of WIPO-TK Task Force comprising of USPTO, EPO, JPO, State Intellectual Property Office of China (SIPO) and Office of Controller General of Patent Design and TradeMark (CGPDTM).

Patent Oppositions

Many Patent Offices world-wide, using Indian TKDL have rejected numerous applications filed for patent in their countries on the ground of no novelty of the invention and as being already cited in the TKDL, therefore these applications are considered a part of the public domain. Many granted patents were objected on the ground that no novelty of the patented invention in view of the information disclosed in the TKDL (Fig. 1). The aspects vary being associated with oppositions in pre-grant and post-grant patent application as founded on the submission of prior art evidenceswhich are well supported by traditional knowledge documentation (Table 1).

TKDL reference citation, as a prior art have led to the significant strides in India. The CGPDTM in India after conclusion of the Access Agreement facilitated TKDL access to the contractual international patent offices. Citations of TKDL references as prior-art have led to noteworthy strides preventing misappropriation of Indian TK.

Revoked Patent(s) in India upon Citing Reference to TKDL

The Central Government in exercise of powers conferred by Section 66 of the Act, declared some patent 'deemed to be revoked' and mentioned the reason like 'prejudicial to the public' in Indian Pat No. 252093 titled 'A synergistic ayurvedic/functional food bioactive composition' granted to M/s Avesthagen Limited. Prior-art evidences by TKDL

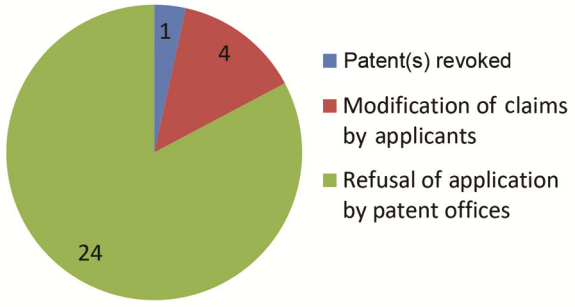

Fig. 1 —TKDL establishing prior art and the fate of some applications in India (2016-2020)

Table 1 — Aspects vary with oppositions in pre-grant and post-grant patent application

Aspects	Pre-grant objections	Post-grant opposition
Nature	Party which is objecting can simply file evidence as a third party and just cannot participate in the process of examination.	Opposing party is part of re-examination process, can submit counter documents and participate in re-examination and hearing process.
Cost	Inexpensive	Highly expensive
Legal support	does not require	Requires
Time period	3 – 20 weeks	4 – 13 years
Documentation	Requires extensive digital documentation.	Does not require extensive documentation.
Appeal by the Patent applicant	No	Yes

are approved in a few of cases by the applicant for example, in Patent No. 1565/CHE/2006 titled '*Eugenia jambolana* plant extracts for the treatment of diabetes and the extraction process thereof' wherein the prior-art acceptance by the applicant leads to the 'application abandoned U/S 21(1)' for example, use of Jamun (*Syzgiumcumini*) for the cure of *Diabetes mellitus*.

Amendment of patent claim(s) by applicants is noticed in numerous applications due to TKDL prior art evidence and few of them are No. 182/ MUMNP/2009, 881/CHENP/2008, 3656/KOLNP/ 2008, 4108/KOLNP/2008, etc. Refusal of patent application on the basis of traditional knowledge as indicated in Controller's decision are No. 1576/DEL/ 2006, 1864/DEL/2006, 1313/DEL/2006, 2426/DEL/ 2007, 692/DEL/2004, 1865/DEL/2006, 369/DEL/2005, 1642/DEL/2006, 3387/DELNP/2004, 1962/MUM/ 2008, 1263/DELNP/2006, 1734/DEL/2007, 1735/ DEL/2007, 907/DEL/2005, 797/KOL/2009, 193/CHE/ 2007, 172/DEL/2007, 212/DEL/2006, 1783/DEL/2007, 1732/DEL/2007, 1927/KOLNP/2010, 833/DEL/2007, 529/KOL/2007,926/CHENP/2010, 1352/MUM/2013, etc.

Indian TKDL has enabled so far numerous withdrawals or cancellation of applications for patent as have claimed rights over the TK regarding usage of various bio-resources. The TKDL authority in 2009 with respect to Indian Systems of Medicine has identified 1155 applications in various Patent Office's including USPTO, EPO, CIPO, UKPTO, IP Australia and Indian IPO. Success with reference to patent applications withdrawn/declared dead/cancelled/ terminated or have the claims been modified or amended by applicant(s) or rejected on certain grounds by the Examiner(s) based on TKDL submissions has been achieved in around 206 cases out of more than 1120 cases (Table 2).In these cases, prior-art evidences from TKDL have been arranged during pre-grant period till August2014.Thus, around 400 applications pending in various other patent offices were challenged. The similar conclusive ending in the remaining applications is expected.

The significant examples of revocation of patents and applications based on TK in India includes bio-piracy bid by a Danish company, ClarasApS for a slimming agent, use of mint for the treatment of bird flu as earlier granted to Chinese Pharmaceutical company-Livzon; an anti-anxiety pill (Ashwagandha) by NatreonInc, America, etc.The EPO has set aside its consideration to grant patents in some cases. Further, many applications were withdrawn by the applicants themselves.

Another interesting case study is of Colgate-Palmolive Company patenting on 'Red Herbal Dentifrice'. The Manufacturers Association of Ayurveda based medicines and furtherprotesters and activists have assumed that the granted patent to Colgate in reference to the herbal dentifrice in the USA, sums to exploitation of traditional knowledge. Since indicated bya lot of news updates, the patent was at largelabeled as a 'bogus patent' by many activists. The chiefapprehension of the association was that the constituents of the composition claimed in the patent included camphor, spearmint, black pepper and clove oil which were already having recognized effects and consequently not patentable.The patent details granted to Colgate, PatNo. US 7,736,629 include; Title: Red herbal dentifrice; Inventors included: Kamath; Shridhara (Mumbai, IN), Nair; Ramesh (Pune, IN); Assignee: Colgate-Palmolive Company; andthe relevant Claim(s) are as follows:

Tooth powder constituents are: (a) Calcium carbonate with distinct properties like- particle size specificity and angularity, efficient to offer gentle a brasives to teeth enamel, for which the specific particle size is selected from the cluster. (b) An effective amount of a red iron oxide which provides red color to the composition andhaving low abrasively was selected in an effectual amount; and (c) then aherbal constituentwith at least one agent or extract with botanical or biological origin was added. The calcium carbonate and red iron oxide were present in a specific weight ratio as referred from thegroup.

Initially an independent claim of the patent claims a composition consisting of calcium carbonate, botanical extract or agent and red iron oxide. For this precise weight and amount of all constituents along with their specific ratios have been offered with accuracy. From the Colgate claim, it was observed that they not only

Table 2 — TKDL outcomes against bio-piracy in various Patent Offices (2016-2020)

Patent Office	Cases
European Patent Office (EPO)	131
United States Patent and Trademark Office (USPTO)	26
Controller General of Patents Designs and Trademarks (CGPDTM)	30
Canadian Intellectual Property Office (CIPO)	37
IP Australia (AIPO)	5
United Kingdom Patent & Trademark Office (UKPTO)	1
Total	230

claim the botanical extract or agent, including clove oil, black pepper, spearmint and camphor as claimed by the Indian association but claims also includes red iron oxide and calcium carbonate besides them. The amalgamation in a specific proportion and weight of traditional ingredients along with red iron oxide and calcium carbonate formulate the composition fit for patent.

After considering prosecution history, it is observed that Examiner cited Patent (6,685,921) which was granted to Procter and Gamble Company as prior art with respect to dental compositions. The patentsdo not edify the exact composition claimed by it, but just disclosethe entire ingredients of the Colgate patent.

In India, there arepatent related family member of Colgate application, viz. Number of application: 3081/DEL/2005; Name of applicant: Colgate-Palmolive Company; Filing date: 18/11/2005; Complete specification date: 18/11/2005; Invention title: "Red herbal dentifrice"; Date of publication: (u/s 11a) 02/10/2009; Status – "Application in amended stage" as found on 27 August 2019. The status found on the Patent Office websitewas- 'the application is so far to be granted'. In the case Indian manufacturers' feels real concernfor this situation; they further canfile a pre-opposition to prevent its grant. Further, person interested may file opposition post grant too. So far TKDL authority and Dabur Company have filed oppositions by means of pre-grant representation.

Though, TKDL helpsPatent Examinersto find the prior-art of Indian biological traditional knowledge related to application for patent, EPO took almost 10 years (1995-2005) to invalidate Neem patent for anti-fungal properties. Similarly in July 2009, to get Enola bean patent cancelled at the USPTO, Mexico had to pursue it for 10 years.[22] Further, cancellation of patent on Soybean to Monsanto at the EPO in July 2007 took 13 years to process.[23]

To avoid misappropriation of TK, TKDL, has a fresh approach and signing of Indian TKDL Access Agreement with EPO and USPTO has been widely covered by media globally. The setting aside and withdrawal/rejection of patent applications at EPO based on TKDL database have also found wide media coverage. The news on TKDL was exposed extensively including ABC News, BBC News, Financial Express, Khaleej Times, London Telegraph, Los Angeles Times, MSN BC, Nature (London), News Flash, Seattle Times, St. Petersburg Times, The Globe and Mail, The Mercury News, The News Tribune, The Wall Street Journal, The Washington Times, Time, Washington News, etc.

Invalidating Patent in Cases of TK Bio-Piracy

At Patent Offices, various patent oppositions are being filed. So far thousands of patent applications filed by commercial entities in different countries have been set aside/ withdrawn/ amended, upon citations of TKDL and so efficiently without wasting much time and neither incurring any additional substantial cost. However, APEDA spent about 70 million Indian Rupees towards legal fee only to get revoke mere few claims of patent in Basmati rice case.

It is observed that the pre-grant patent oppositions are relatively inexpensive and efficient. Since such pre-grant patent oppositions may be filed by any person while only an interested person may file post-grant patent oppositions and so it becomes expensive and time taking too. In view of these, awareness on such aspects including bio-piracy, TK, TKDL, etc. needed among the public in large so that a timely pre-grant opposition any be raised to prohibit wrong patenting and to escape the later burden of post-grant patent oppositions.

Indigenous people and local communities need awareness on IPR and its linkages with TK so that they make knowledgeable decisions commercializing the concern TK by means of patent or other IPR. The IPR system includes mechanisms to modify or revoke rights that were granted to creations and innovations which failed to fulfill criteria of patent. Anyway, the publication on such related issues will certainly recognize and empower indigenous communities by inspiring them to further creation and innovation and to then in turn they can make benefit from the IPR system.

Assessment of TKDL Reference Objecting Patent

Such database does not provide any enabling disclosure for, how a person may use/apply accurate measures for producing medicine from plant. Thus, it is inappropriately assessed by scholars that restricting patent as per citation of TKDL is not momentous in protecting Ayurvedic medicine.[24] The effectiveness of the TKDL has been reflected in a study conducted in 2011 which showed a 44% decline in patent applications regarding Indian traditional medicine systems and medicinal plant preparations at the European Patent Office.[14]

TKDL at International Plat form

From time to time, on different occasions, TKDL model have been used successfully.[25] In June 2005, at

the Regional Consultation on Development of Traditional Medicines in the South East Region of Korea,one of the recommendations opted was "WHO should develop a model framework on replication of Traditional Knowledge Digital Library (India) suitable for adapting to individual country needs" (WHO, 2000).[26] The National Knowledge Commission, Government of India, in 2007, suggested the wayto use, apply and incorporate TKDL, with all appropriate sources of information, into the lists of minimum search documentation of Search Authorities internationally and rest of the offices, during patent applications processing.[27]In August 2003, the Director General, WIPO, mentioned that, "One recent tangible outcome of India's strong involvement was the adopting by Inter-governmental Committee Technaical standards concerning TK documentation". Earlier in 2003, he expressed that, "TKDL presentation at IGC brought strong recognition for leading work of India in the fields of traditional knowledge" (TKDL).In 2011, WIPO in collaboration with CSIR in New Delhi organized an International Conference on 'Utilization of Traditional Knowledge Digital Library as a Model for Protection of Traditional Knowledge'.[28] Further, in order to promote replication of TKDL by other countries, WIPO in association with Department for Promotion of Industry and Internal Trade and CSIR, organized an 'International Study Visit to TKDL'for 19 countries.[29] Propositions can be summarized in the following ways:

(i) International bodies should request to the member nations to adopt model of Indian TKDL as their national model for protection of their concern national TK.
(ii) Support at international forum is required at priority to get country-wise TKDL and to be included as PCT minimum documentation to prevent bio-piracy and misappropriation.
(iii) Such TK database may be recommended to be used as source of prior art citable for novelty and/or inventiveness to prevent grant of incorrect patents.
(iv) More and objective based Progammes are required for adequate awareness on the subject TK among the stakeholders.

In 2022, the Cabinet (GoI) approves widening access of the TKDL to users too. However, such access is phase-wise opening and a paid one. The recent COVID-19 pandemic has also been witnessing extensive use of Indian TK particularly the traditional medicines benefitting from immune-boosting to symptoms-relief to anti-viral activity. Earlier in April 2022, the World Health Organization (WHO) established its first off-shore Global Centre for Traditional Medicines (GCTM) in India. These demonstrate the continued relevance of TK in addressing the current and emerging needs of the world.[30]

Conclusion

It is suggested that every country should create and maintain database codifying national TK as a help to establish non-patentability of such TK which are lacking 'novelty' and 'non-obviousness' and therefore may regulate erroneous patenting. Incorrect patenting will be checked, once all the TK particularly the medicinal plants/biological resources associated knowledge is documented and made accessible to the patent examiners as already happened successfully for Indian TKDL. The TKDL is well appreciated at World Intellectual Property Organization (WIPO) and it is recommended that all countries must develop such electronic database of their TKs. TK which later-on will be merged internationally, that will be an aid to examine patentability of the invention applied for the patent.

References

1 Jachak S M & Saklani A, Challenges and opportunities in drug discovery from plants, *Current science*, 92 (2007)1251.
2 Baumgartner C, Exclusion by inclusion? On difficulties with regard to an effective ethical assessment of patenting in the field of agricultural bio-technology, *Journal of Agricultural and Environmental Ethics*, 19(6) (2006) 521.
3 Crouch N R, Douwes E, Wolfson M M, Smith G F & Edwards TJ, South Africa's bio-prospecting, access and benefit-sharing legislation: Current realities, future complications, and a proposed alternative, *South African Journal of Science*, 104 (9-10) (2008) 355-366.
4 Janis M & Kesan J, Intellectual property protection for plant innovation: Unresolved issues after *J.E.M.* v *Pioneer*, *Nature biotechnology*, 20 (11) (2002) 1161.
5 Mashelkar R A, General D & Bhawan A, Intellectual property rights and the Third World, *Current Science*, 81(8) (2001) 955.
6 Pant A & Moorthy A L, Knowledge management and safeguarding Indian traditional knowledge, *Annals of Library and Information Studies*, 60 (2) (2013) 88.
7 Mulik K & Crespi J M, Geographical indications and the Trade Related Intellectual Property Rights Agreement (TRIPS): A case study of basmati rice exports, *Journal of Agricultural& Food Industrial Organization*, 91 (4) (2011) 1.
8 Vivekanandan P, Prakash T N, James P D, Patel R, Verma S R, Sahu B & Gupta A K, Protecting traditional knowledge of small, scattered and disadvantaged grassroots innovators and traditional knowledge holders: Honey Bee Perspective, *Agenda for Policy and Institutional Change,* 2004, 1.
9 Moreira A C, Müller A C A, Pereira Jr N & Antunes AMDS, Pharmaceutical patents on plant derived materials in Brazil:

Policy, law and statistics, *World Patent Information*, 28(1) (2006)34.
10 Bodeker G, Traditional medical knowledge, intellectual property rights and benefit sharing, *Cardozo J Int'l Comp L,* 11 (2003) 785.
11 Chakravarty R & Mahajan P, Preserving traditional knowledge: Initiatives in India, *IFLA Journal*, 36(4) (2010) 294.
12 Hirwade M, Protecting traditional knowledge digitally: A case study of TKDL, In: *National Workshop on Digitization Initiatives and Applications in Indian Context*, DNC, Nagpur, 3 January 2010.
13 Farooq S, Majeed A, Khan N, Bhat Z & Roohi M, Legal framework on protection of traditional knowledge: A review, *International Journalof Advanced Research in Science and Engineering*, 8(1) (2019) 100.
14 PIB, India and Japan Sign TKDL Access Agreement, Press Information Bureau, Government of India, 2017.
15 Gupta V K, Traditional Knowledge Digital Library, In *Conference Proceedings of Sub-Regional Experts Meeting in Asia on Intangible Cultural Heritage*, Bangkok, Thailand, 2005.
16 Hirwade M & Hirwade A, Traditional knowledge protection: An Indian prospective, *DESIDOC Journal of Library& Information Technology*, 32 (3) (2012) 240.
17 Mashelkar R A, General D, Bhawan A, Intellectual property rights and the Third World, *Current Science*, 81 (8) (2001) 955-965.
18 Ansari M S, Evaluation of role of Traditional Knowledge Digital Library and Traditional Chinese Medicine Database in preservation of traditional medicinal knowledge, *DESIDOC Journal of Library & Information Technology,* 36 (2) (2016) 73.
19 Nadkarni A & Rajam S, Capitalising the benefits of Traditional Knowledge Digital Library (TKDL) in Favour of Indigenous Communities, *NUJS L Review,* 9 (2016) 183.
20 Graham S J, Hall B H, Harhoff D & Mowery D C, Post-issue patent 'quality control': A comparative study of US patent Re-examinations and European patent oppositions, In: Cohen WM & Merrill SA, editors, *The Patent System in the Knowledge-Based Economy*, Washington, DC: National Academies Press, 2002.
21 Scaria A G & Dedeurwaerdere T, *Towards a Contractually Created Commons in Traditional Knowledge and Genetic Resources for Scientific Research and Innovation in India: Scope and Challenges*: Proceedings of the First IASC Thematic Conference on the Knowledge Commons, UCL Louvain-la-Neuve, Belgium. 12-14 September2012.
22 Michon F, Moore S, Fusco P, Wohlstadter S, Davis C, Coleman D & Joshi K,US PatNo 11/255,161, 2006.
23 Staford N, GM patent rejected after 13 year, *Nature,* 2017.
24 Protection of traditional knowledge by utilization of TKDL, Press Information Bureau, Ministry of Science & Technology, Government of India, 21 March 2011.
25 http://www.tkdl.res.in/tkdl/langdefault/common/Biopiracy.asp?GL=Eng.TKDL, 20 February 2020.
26 WHO, General guidelines for methodologies on research and evaluation of traditional medicine, Geneva: World Health Organization, 2000.
27 Babu RR, Protection of Traditional Knowledge and Expressions of Folklore: Locating India in the Global Framework, In *Locating India in the Contemporary International Legal Order*, Springer, New Delhi, 2018.
28 WIPO, Protecting India's Traditional Knowledge, WIPO Magazine, 2011.
29 https://www.csir.res.in/documents/tkdl, CSIR (accessed on 4September2020).
30 https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1852530 (accessed on 17 August 2022).