Economic, social and cultural rights in India: Opportunities for advocacy in intellectual property rights

The Traditional Knowledge Digital Library

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This is part three of a three-part case study that considers the International Covenant on Economic, Social and Cultural Rights (ICESCR) through aspects of intellectual property in India, namely, mobile patents, free and open source software, and India's Traditional Knowledge Digital Library. Through these, it demonstrates the potential of these technologies in realising ESCRs and makes suggestions as well. The discussion below should be read in conjunction with the synthesis overview. These case studies have been produced as part of the Association for Progressive Communications (APC) research project Connecting your rights: Economic, social and cultural rights (ESCRs) and the internet.[1] This is a three-year project funded by the International Development Research Centre (IDRC).

[1]For more information, see: https://www.apc.org/en/projects/connecting-your-rights-economic-cultural-and-socia

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1. Background

The first problem one encounters in studying traditional knowledge (TK) is the extent and meaning of the term itself. No globally accepted definition of TK exists, and therefore no clear delineation of its scope. The definition adopted by the World Intellectual Property Organization (WIPO) is that "TK is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity."[2] TK embraces traditional cultural expressions (TCEs), including folklore, within its ambit, and includes distinctive signs and symbols associated with traditional knowledge.[3] However, the scope of this study does not extend to TCEs, as they necessarily would fall under the purview of copyright law.

Before we frame TK in terms of economic, social and cultural rights (ESCRs), let us understand the phenomenon of biopiracy in a bit more detail using two examples, one connected to the right to food, and the other connected to health, which we shall explain in more detail later. Biopiracy is the use of intellectual property (IP) systems to legitimise control over biological products or processes that were previously used for centuries in non-industrialised cultures.[4] The case of neem-related patents, through which bio-prospectors attempted to appropriate the full economic gains arising from a plant whose medicinal value was already in the public domain, is well documented.[5] Another case worth noting is that of the "Enola bean", in which Larry Proctor, a United States (US) citizen, purchased a package of Mexican beans of various colours, separated out the yellow ones, and spent three years selectively breeding the plants. He then named his line "Enola" and obtained patent protection for the bean, its plant, its pollen, and the method of producing it.[6] This case is far more worrying than the neem case for two reasons.[7] First, it was a case that had an immediate and tangible impact on the producers of the commodity, in that yellow Mexican beans were exported into the US before the patent was granted, and the assertion of the patent led to significant reductions in bean exports, representing a quantifiable economic loss for bean farmers.[8] Second, the patent was allowed to stand for almost a decade, amounting to half the life of a legitimate patent.[9] This represents an incredibly unjust outcome – an invention ("specifically selected yellow beans") arising from traditional knowledge in the public domain (since Mexican farmers had been cultivating and exporting these beans) being monopolised by a private entity illegally for almost a decade.

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[2]Traditional Knowledge, WIPO. www.wipo.int/tk/en/tk

[3]WIPO. (2010). List and Brief Technical Explanation of Various Forms in which Traditional Knowledge May be Found. www.wipo.int/meetings/en/doc_details.jsp?doc_id=147152

[4]Shiva, V. (2001). Protect or Plunder? Understanding Intellectual Property Rights. London: Zed Books.

[5]See, e.g., Horsbrugh Porter, A. (2006, 17 April). Neem: India's tree of life. *BBC*. news.bbc.co.uk/2/hi/south_asia/4916044.stm; BBC. (2005, 9 March). India wins landmark patent battle. *BBC*. news.bbc.co.uk/2/hi/science/nature/4333627.stm; Hoggan, K. (2000, 11 May). Neem tree patent revoked. *BBC*. news.bbc.co.uk/2/hi/science/nature/745028.stm

[6]In re POD-NERS, L.L.C., Re-examination No. 90/005,892, US Fed. Cir. 2009. law.justia.com/cases/federal/appellate-courts/cafc/08-1492/08-1492-2011-03-27.html

[7]It is also noteworthy for another reason: it is illustrative of the time and effort required to contest claims after a patent has been granted. Proponents of the TKDL would argue that what took a decade in the Enola bean case could have been achieved in a manner of weeks at the application stage by a patent office equipped with such a database.

[8]Shashikant, S., & Asghedom, A. (2009, 12 August). The 'Enola Bean' dispute: patent failure & lessons for developing countries. *Third World Network*. twn.my/title2/wto.info/2009/twninfo20090811.htm

[9]Crouch, D. (2009, 10 July). Mexican Yellow Bean Patent Finally Cooked. *Patently-O*. patentlyo.com/patent/2009/07/mexican-yellow-bean-patent-finally-cooked.html

The differences between TK and other forms of IP are the following:

- With other forms of IP, property rights are afforded to the innovator or creator, whereas communities own TK.
- Other forms of IP are designed as incentive mechanisms for the creation of new property, whereas there is no such incentive to create new property with TK.
- IP is also time-bound, whereas TK is held in perpetuity from generation to generation. The invention under IP must also satisfy the requirement for novelty and industrial application, whereas TK is informal, and occurs over a period of time.

Although IP is not tailored to protect TK, it has been used to prevent misappropriation of TK is some instances that we will discuss below.

At the turn of the millennium, an expert group found that roughly 2,000 patents linked to India's TK in medicine were being granted annually around the world.[10] This expert group proposed the establishment of the Traditional Knowledge Digital Library (TKDL),[11] "a home-grown effort to ensure patent offices around the world do not grant patents for applications founded on India's wealth of TK that has existed for millennia."[12] This was done in order to reduce biopiracy, and in 2001 India launched the initiative, which digitised its wide repository of TK with the hope of enabling the protection and preventing the misuse of this knowledge. It is essentially a digital knowledge repository of Indian traditional knowledge about medicinal plants and formulations used in Indian systems of medicine, including Ayurveda, Siddha, Unani and yoga.[13] The TKDL's appeal lies in the manner in which it approaches attempts to patent prior art (the "state of the art") – it serves to pre-empt the granting of a patent, rather than to contest a patent's validity after it has been granted. This, it is claimed, reduces the time taken to contest claims from a matter of years to a few weeks.[14]

In this study, the TKDL has been examined as a primary strategy for the protection of TK. It might seem odd to cover TK in a report focussing on the internet, but TK is implicated in information societies as it is used to produce information-embedded products and services. The internet's relevance to TK, more specifically, is found through databases like the TKDL which thwart biopiracy and other forms of inappropriate appropriation. The TKDL limits misuse of TK by preventing patents from being granted to inventions derived from TK. Misuse of TCE, however, would require protection in terms of copyright, which is not within the ambit of the TKDL. Consequently, the focus of this study remains specifically on the protection of TK and the extent to which the TKDL is effective in this regard.

2. Defining the rights involved

2.1. Article 11

Article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the right of everyone to an adequate standard of living, including adequate food, clothing and housing, and

[10]Gupta, V. K. (2011). Protecting Indian Traditional Knowledge from Biopiracy. WIPO. www.wipo.int/export/sites/www/meetings/en/2011/wipo_tkdl_del_11/pdf/tkdl_gupta.pdf

[11]www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng

[12]Gupta, V. K. (2011). Op. cit.

[13]www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng

[14]Press Information Bureau. (2010, 28 April). India Partners with US and UK to Protect Its Traditional Knowledge and Prevent Bio-Piracy. pib.nic.in/newsite/erelease.aspx?relid=61122

to the continuous improvement of living conditions. Article 11(2)(a) mandates that states parties to the Covenant take measures to "improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources."[15] Traditional knowledge is connected to food in multiple ways, like ecosystem and landscape management, water management, soil conservation, biological control of pests and diseases, ecological agriculture and livestock practices, and plant and animal breeding – and most importantly, breeding and preserving varieties of plant and animal species. Suman Sahai, founder of the Gene Campaign,[16] helps us understand the connection between food security and traditional knowledge. She argues that farmers are a community of women and men who have not only created several thousand breeds of food and cash crops, but also "identified valuable genes and traits in these crops and maintained them over generations through a highly sophisticated system of crossing and selection."[17] This would, in effect, prevent monoculture, which refers to a situation in which the number of species of crops is limited, making the damage that pests can do uncontrolled.

2.2. Article 15

Communities

Protection of TK can be primarily placed within Article 15 of the ICESCR. In order to understand the relationship between TK and Article 15, we must first appreciate that TK is also scientific knowledge. There are two ways in which the right of the TK community can be mapped onto Article 15. First, the Article recognises "the right to take part in cultural life," and second, "to enjoy the benefits from scientific progress and its applications." This ensures that communities have the right to continue to operationalise and use TK. Further, Article 15 includes the right "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production." However, while this is a universal right, in practice it will only happen when national law recognises the property rights of the community, facilitates protection of these rights, takes legal action against infringements, and provides mechanisms for the collection and distribution of royalties. What might not strike the reader as obvious is that the benefits of protecting the moral and material interests in the world of TK accrue to the community, while in other forms of IP the rights holder is either an individual or corporation. In this way TK works differently to the human rights framework, where the rights holder is the individual.

The general public

The general public, or individuals, have rights in terms of TK too, particularly as it relates to the first part of Article 15, i.e. "the right of everyone to enjoy the benefits of scientific progress and its applications." It therefore follows that TK should not be restricted to or contained within a particular community, and must be allowed to benefit individuals outside of that community. There are two ways in which individuals can be prevented from benefiting from TK. One, a corporation can manage to privatise that knowledge through biopiracy; and two, the community might not share the TK with the general public. The therapeutic properties of turmeric, for example, are widely known in India, but in contrast, mrigasira, the

[15] www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[16] genecampaign.org

[17] Sahai, S. (1996). Importance of Indigenous Knowledge in IPR. *Economic and Political Weekly, 31*(47).

so-called "fish medicine" for asthma, a concoction of live sardines smeared with secret herbs, is not publicly known. While the rights of the community need to be protected from commercial exploitation, these interests must also be balanced against similar rights of the general public.

Article 15(2) also mandates that states take necessary steps for the conservation, development and diffusion of science and culture, neatly capturing the dynamic of the rights of communities versus the rights of the general public.

3. Rights holders and duty bearers

3.1. Rights holders

Following from the above, the rights holders in this context are:

- *Traditional communities:* Patents granted for TK amount to commercial exploitation of knowledge that is collectively held by a community, often to the exclusion of the community's own use of the knowledge. Further, attribution of the innovation to the TK holders is usually lost when such an innovation is patented and marketed by corporations.
- *The general public:* TK can be of great value to the general public, especially in the areas of food security and health.

3.2. Duty bearers

The following state institutions are relevant duty bearers in this context:

- *The Council for Scientific and Industrial Research (CSIR)* is an autonomous body that engages in research and development in the areas of science and technology. The CSIR is "strengthening its patent portfolio to carve out global niches for the country [India] in select technology domains."[18]
- *The Department of Ayurveda, Yoga and Naturopathy, Unnani, Siddha and Homeopathy (AYUSH),* a unit within the Ministry of Health and Family Welfare, is a government body in India that is responsible for developing research in these and other alternative medicine systems.

A collaboration of both of the above resulted in the creation of the TKDL, which was funded by the CSIR.[19] As mentioned, this is digital repository of traditional knowledge, including medicinal plants and medicinal formulations used in Indian systems of medicine.

- *The Department of Indian Policy and Promotion (DIPP)*, in its Intellectual Property Rights Policy of 2016, established its vision for working towards "an India where intellectual property rights promote advancement in science and technology, arts and culture, traditional knowledge and biodiversity resources."[20]
- *The Controller General of Patents, Designs and Trademarks of India (CGPDT)* published in 2012 the Guidelines for Processing of Patent Applications relating to Traditional Knowledge and Biological Material, which lays out the process of screening applications, allotments, examination, assessment of novelty and invention, etc.[21]
- *The Intellectual Property Appellate Board* hears appeals against decisions of the CGPDT.

[18] www.csir.res.in/Home.aspx?MenuId=2

[19] www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng

[20] dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf

[21] ipindia.gov.in/iponew/TK_Guidelines_18December2012.pdf

- *The National Biodiversity Authority (NBA)* "performs facilitative, regulatory and advisory functions for the Government of India on issues of conservation, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of biological resources."[22] The United Nations Convention on Biological Diversity (CBD), which entered into force in 1993, establishes the sovereign rights of states over their biological resources. The CBD also provides for equitable sharing of benefits arising from the use of TK with holders of the knowledge. TK is also dealt with under the umbrella of associated knowledge within various provisions of the Indian Biological Diversity Act, 2002, and its Rules from 2004.[23]

4. Existing situation

The TKDL targets Indian systems of medicine available in the public domain. These areas are being documented by collating the information on traditional knowledge from literature existing in local languages such as Sanskrit, Urdu, Arabic, Persian and Tamil in digitised format. The information has been made available in five international languages, which are English, German, Spanish, French and Japanese. Since the inception of the TKDL, in just under two years, and in Europe alone, India has succeeded in using this resource to bring about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations. While it is clear that the first three systems of medicine, i.e Ayurveda, Unani and Siddha, are systems that have active ingredients, the concept of yoga being a system of medicine is unclear, as there is no medicine administered to the patient. Increasingly, however, medical procedures are being patented, and the Indian government in August 2015 shortlisted 1,500 yoga asanas to be included in the TKDL to prevent foreign parties from patenting them.[24] This was not the first move of its kind, and followed several yoga-related patents being applied for[25] and granted[26] around the world, notably in the United States.

Between 2001 and 2015, out of a total of 189 pharmaceutical applications, which include medicines, therapeutics, etc., 21 were granted while 17 were rejected. An additional 30 were deemed withdrawn and another 31 were abandoned. At the time of writing, 90 have their examination still in progress. Out of the 10 applications under cosmetics, seven are in progress while one each has been accepted, rejected and deemed to be withdrawn. There was only one application under agriculture, which was rejected. The domain of food had three applications, out of which one was rejected, one deemed to be withdrawn, and the last one is in progress.[27]

India and the US had the maximum number of applications at 75 and 43 respectively. Japan and South Korea were third and fourth at 16 and 11 respectively. Most of these applications were in progress at the time of reporting, with 12 of India's applications being rejected and 17 being abandoned. Only five patent applications had been granted to India while three were deemed to be withdrawn; 38 of India's

[22] nbaindia.org/content/22/2/1/aboutnba.html

[23] nbaindia.org/content/19/16/1/faq.html

[24] PTI. (2015, 9 August). Over 1500 yoga asanas shortlisted to thwart patenting by foreign parties. *Indian Express*. indianexpress.com/article/india/india-others/over-1500-yoga-asanas-shortlisted-to-thwart-patenting-by-foreign-parties

[25] TNN. (2007, 18 May). US patent on yoga? Indian gurus fume. *Indian Express*. timesofindia.indiatimes.com/india/US-patent-on-yoga-Indian-gurus-fume/articleshow/2058285.cms

[26] Lee, T. B. (2013, 13 December). A yoga patent? Here's why the USPTO approves so many dubious applications. *Washington Post*. https://www.washingtonpost.com/news/the-switch/wp/2013/12/13/a-yoga-patent-heres-why-the-uspto-approves-so-many-dubious-applications

[27] www.tkdl.res.in/tkdl/langdefault/Common/ExaminerReport.asp?homepage=sub

applications and 12 of those from the US are pending. Taiwan's and Jordan's only applications were granted, while Spain's only application was rejected.[28]

While proponents of the database have been vocal in their vision for its application, it has received criticism on several grounds.

There exists a fair amount of disagreement regarding the best possible means through which TK can be protected.[29] Indeed, existing literature already features catalogues of international law (both "hard" and "soft"), regional norms, and domestic legislation that accords protection to TK within the framework of culture.[30] While some believe that data aggregation and record creation is the best means to tackle biopiracy, others propose different approaches,[31] such as negotiating access agreements between indigenous communities and bioprospectors.[32]

The TKDL has also attracted criticism because of its high level of confidentiality. In response to a Right to Information (RTI) application, the CSIR clarified that the TKDL can only be accessed by foreign patent offices.[33] It is not made available to the Indian Patent Office or to CSIR scientists. As per the same response, the decision to make the TKDL confidential was taken during a cabinet meeting in 2006, but there exists no legal instrument that mandates such confidentiality.

TK databases in other countries do not impose access restrictions. The Korean Traditional Knowledge Portal, for example, explicitly states the motivation behind making itself publicly available:

> The database is presented on-line through the Korean Traditional Knowledge Portal (KTKP). The reasons for making the database publicly accessible through the KTKP are as follows:
>
> 1. To lay the foundation for international protection of Korean traditional knowledge, thereby preventing unauthorized use of patents inside and outside the country.
> 2. To provide an abundance of information on traditional knowledge and related research, thereby expediting the development of related studies and industries.
> 3. To provide essential information for patent examinations, thereby enhancing the quality of intellectual property applications for traditional knowledge.[34]

Similarly, the contents of the China Traditional Medicine Patent Database are also publicly available on the internet.[35]

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[28]Ibid.

[29]WIPO. (2010). Op. cit., Annex 2.

[30]See, e.g., Coombe, R. J. (2005). Protecting Traditional Environmental Knowledge and New Social Movements in the Americas: Intellectual Property, Human Right, or Claims to an Alternative Form of Sustainable Development? *Florida Journal of International Law, 17*(1), 115-136.

[31]Swiderska, K. (2006). *Banishing the Biopirates: A New Approach to Protecting Traditional Knowledge*. International Institute for Environment and Development. pubs.iied.org/pdfs/14537IIED.pdf

[32]Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. (2002). *Review of Existing Intellectual Property Protection of Traditional Knowledge*. WIPO. www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/wipo_grtkf_ic_3_17-main1.html

[33]Reddy, P. (2012, 29 March). Is the TKDL a 'confidential database' and is it compliant with Indian copyright law? *SpicyIP*. spicyip.com/2012/03/is-tkdl-confidential-database-and-is-it.html

[34]KTKP Introduction, Korean Traditional Knowledge Portal. www.koreantk.com/en/m_about/about_01.jsp?about=1

[35]Brief introduction of China Traditional Medicine (TCM) Patent Database, China TCM Patent Database. 221.122.40.157/tcm_patent/englishversion/help/help.html

Even before the TKDL project reached completion, some scholars wondered whether it could, in the wrong hands, serve as an invaluable tool to facilitate biopiracy.[36] The implementation of the project, which restricted access to the database to patent offices alone, and controlled the distribution of the aggregated data through the use of non-disclosure agreements, sought to address such concerns.[37] However, this seems to be highly illogical, since the TKDL has not aggregated any knowledge that was not already in the public domain.

There seems to be no reason to keep a valuable resource such as the TKDL away from the public's reach, especially considering the fact that the entire project, funded by the CSIR, was bankrolled by the Indian taxpayer. Restricting access to the TKDL severely limits the benefits that the general public could derive from this knowledge. Even if one were to accept that there exist compelling reasons to keep the data confidential, it is clear that the TKDL, by its very nature, cannot possibly be invulnerable to breach. Problems of access control are endemic to large databases – it has been postulated that large aggregations of secret data are fundamentally impossible because security must be traded off for ease of access in such situations. Thus, "you cannot construct a database with scale, functionality and security because if you design a large system for ease of access it becomes insecure, while if you make it watertight it becomes impossible to use."[38] For this reason, governments have been urged to make use of centralised databases only when absolutely necessary.[39] If we accept the premise that centralised databases cannot possibly be both accessible and secure, then we must examine whether the TKDL represents a balanced trade-off between accessibility and confidentiality.

The TKDL has also raised questions of copyright, with claims that it falls foul of the Indian Copyright Act, 1957, since it has digitised works (such as translations or compilations of ancient texts) that are still under copyright without the consent of their authors.[40] Responding to the same RTI application discussed above, the CSIR claimed that no consent was required since the traditional knowledge in question was authored many years ago. This is a perplexing position to take as there is significant skill and labour involved in translating and compiling these ancient texts and putting this knowledge together, which merits copyright protection.[41]

5. Rights framework

As mentioned, India has signed the Convention on Biological Diversity (CBD), a treaty with 194 parties in total.[42] The CBD provides for the respect, preservation and maintenance of "knowledge, innovation and practices of indigenous and local communities embodying traditional lifestyles relevant for the

[36]Sharma, D. (2002). Digital Library on Indian Medicine Systems: Another tool for biopiracy. *Economic and Political Weekly, 37*(25).

[37]Oguamanam, C. (2008). Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation. *Indiana Journal of Global Legal Studies, 15*(2).

[38]Proposed by Ross J. Anderson, this rule of thumb has come to be known as Anderson's Rule. See: Porter, H. (2009, 10 August). Nine sacked for breaching core ID card database. *The Guardian*. www.theguardian.com/commentisfree/henryporter/2009/aug/10/id-card-database-breach

[39]See, e.g., Anderson, R. et. al. (2009). *Database State*. Joseph Rowntree Reform Trust. www.jrrt.org.uk/sites/jrrt.org.uk/files/documents/database-state.pdf

[40]Reddy, P. (2012, 29 March). Is the TKDL a 'confidential database' and is it compliant with Indian copyright law? *SpicyIP*. spicyip.com/2012/03/is-tkdl-confidential-database-and-is-it.html

[41]Reddy, P. (2012, 21 April). The need for an 'independent' review of the TKDL project. *SpicyIP*. spicyip.com/2012/04/need-for-anindependent-review-of-tkdl.html

[42]List of Parties, Convention on Biological Diversity. https://www.cbd.int/information/parties.shtml

conservation and sustainable use of biological diversity,"[43] and also for encouraging the wider application of such practices while ensuring that the benefits arising from such utilisation are shared equitably with the communities in question.[44] Having signed this convention, India has the duty to protect this knowledge without appropriating it, and the TKDL is a means to protect this right.

Such provisions have been enunciated in India's Biological Diversity Act.[45] Restrictions on the granting of patents for inventions arising from research on biological resources,[46] the transfer of biological resources or knowledge,[47] and the enforcement of equitable benefit sharing[48] aim to serve as effective legal bars to biopiracy and unauthorised use of traditional knowledge.

In addition to the CBD-based rights mechanisms protecting TK innovations, norms instituted by other international bodies exist to safeguard the rights of indigenous communities. One specific example in this context is the World Health Organization's approach to Traditional and Complementary Medicine (T&CM), in which it urges states to "prevent the misappropriation of T&CM by implementing the relevant international instruments in line with the WHO global strategy and plan of action on public health, innovation and intellectual property, adopting or amending national intellectual property legislation, and enacting other defensive protection strategies."[49]

Under the Biological Diversity Rules, 2004, the general functions of the National Biological Diversity Authority include the duty to "(xiii) take steps to build up data base and to create information and documentation system for biological resources and associated traditional knowledge through bio-diversity registers and electronics databases to ensure effective management, promotion and sustainable uses."[50]

Thus, there exists a whole host of international and national norms, both of a general and a specific nature, enunciating the right of indigenous communities to the inventions that arise from their traditional knowledge. It would be desirable to have legislation specifically dealing with this. The Indian government planned to introduce legislation on the protection of traditional knowledge in 2002 with a view to protect it under the international patent regime,[51] but that did not materialise.

6. Ask from civil society

For the reasons stated above, the access policy of the TKDL requires significant modification if the database is to reach its true potential for providing accurate, efficient and time-bound protection to TK-based innovations through the use of a centralised database that is wired into a network of interested parties.

[43]Article 8(j) of the Convention on Biological Diversity. https://www.cbd.int/convention/text

[44]Ibid.

[45]nbaindia.org/content/25/19/1/act.html

[46]Section 6 of the Biological Diversity Act.

[47]Section 20 of the Biological Diversity Act.

[48]Section 21 of the Biological Diversity Act.

[49]World Health Organization. (2013). *WHO Traditional Medicine Strategy 2014-2023*. apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1

[50]Section 12, National Biological Diversity Rules, 2003.

[51]PTI. (2002, 4 September). Government planning legislation on traditional knowledge. *The Economic Times*. articles.economictimes.indiatimes.com/2002-09-04/news/27333499_1_traditional-knowledge-govt-planning-legislation-outreach

6.1. The need to push for open knowledge

A system like the TKDL constitutes a mechanism for defensive protection of TK – it seeks to keep TK in the public domain rather than to exclusively put it in the hands of the community that evolved it. This is similar to the Peer to Patent[52] initiative which ensures that more eyes are involved in following the process: a crowd-sourced approach to preventing inappropriate appropriation. The doctrine of prior art is essential to such forms of protection. The success or failure of defensive protection strategies rests on two aspects: a legal element and a structural one.

6.2. The need to address legal barriers

Primarily, the TKDL's data seems to be far from infallible, with several reports of mistranslations[53] and exaggerated claims[54] made by the CSIR. Apart from this, the most important requirement that the TKDL must fulfil is for its data to meet the legal criteria established for prior art in various jurisdictions. This would entail ensuring that the knowledge is made available with clear evidence of the date of its publication, and the presentation of the knowledge in a manner that clearly establishes that a patent claim is anticipated by the data contained in the library.[55] Further, the fundamental challenge faced by any defensive protection mechanism is its vulnerability to differing definitions of prior art in various jurisdictions:

- European Patent Convention (EPC): The most TKDL-friendly jurisdictions are those such as the European Union (EU). The EPC defines prior art as "everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."[56] Thus, innovations detailed in the works indexed by the TKDL would fall within the definition of prior art, and therefore be unpatentable – assuming, of course, that all the works digitised and translated by the database were publicly available. An overwhelming majority of the TKDL's self-proclaimed "successes" have been achieved in the EU – around 120 of the 180 "successful outcomes" are against European patent applications.[57]
- United States: On the other end of the spectrum is the US definition of prior art. The United States Patent Act provides that a person "shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."[58] This effectively excludes protection for any non-published knowledge outside the US. Further, given the restrictive access to the TKDL, it appears that the database would not fall within the definition of a "printed publication", since it has never been "published" – merely circulated among patent examiners on conditions of non-disclosure. Thus, it appears that there is no legal basis for the

[52] www.peertopatent.org

[53] Rathi, M. (2012, 20 April). Guest Post – TKDL: A success – Really? *SpicyIP*. spicyip.com/2012/04/guest-post-tkdl-success-really.html

[54] Reddy, P. (2012, 19 March). Guest Post: The Traditional Knowledge Digital Library and the EPO. SpicyIP. spicyip.com/2012/03/guest-post-traditional-knowledge.html

[55] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. (2003). *Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System*. WIPO. www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_6.pdf

[56] Article 54(2) of the Convention on the Grant of European Patents. https://www.epo.org/law-practice/legal-texts/epc.html

[57] Outcomes against bio-piracy, Traditional Knowledge Digital Library. www.tkdl.res.in/tkdl/langdefault/common/Outcome.asp

[58] 35 U.S.C. § 102(a).

TKDL to be cited as evidence of prior art in the US, or other jurisdictions that have similar definitions of prior art.[59]

6.3. The need to address structural barriers

In choosing to characterise itself as an archive of prior art, the TKDL has placed the burden of enforcing TK assertions upon patent examiners around the world. In doing so, it has pigeonholed itself into a doctrine (namely prior art) that has a tendency to go largely unheard in patent examinations. With studies showing that more experienced patent examiners, typically occupying higher positions in the patent office, are less likely to cite examples of prior art in their examinations,[60] and still other evaluations showing that applicants for patents are extremely unlikely to provide and identify prior art surrounding their claims,[61] it is evident that there are structural imbalances working against the efficacy of the prior art doctrine in preventing illegitimate patent claims. Thus, efforts must be made to counter this imbalance at two levels: first, access to the TKDL must be made as easy as possible; second, the TKDL has to undertake affirmative patent monitoring efforts.

Patent monitoring, while an onerous and expensive task, is nevertheless necessary for the success of a defensive system such as the TKDL, especially in those jurisdictions which do not have the legislative framework to enable provisions of the CBD that mandate disclosure of genetic material sources.[62]

7. Advocacy actors

- *CSIR:* The TKDL is currently operated under the CSIR, and there may therefore be a potential conflict of interest with respect to patent applications filed by government-controlled organisations, particularly the CSIR itself. By its own admission, the CSIR has the largest patent portfolio among all publicly funded R&D institutions in India, and its stated goal is to strengthen India's patent portfolio.[63] The CSIR is, however, a potential advocacy partner in civil society mobilisation around this issue.
- *Gene Campaign:* The Gene Campaign, set up in 1993 by Dr. Suman Sahai, aims to make "agriculture sustainable and climate resilient; improving household food and nutrition; agrobiodiversity conservation and use; community-led seed production; integrated farming for village development; rights empowerment, training and capacity building; documentation & protection of indigenous knowledge; public education and awareness generation; and policy advocacy."[64] Sahai is of the opinion that traditional knowledge needs to be recognised as a technology, to protect it from being diluted and to ensure that there is a benefit-sharing arrangement in place.[65] This is an area that civil society can actively pursue. The main challenge in securing recognition is the general scepticism towards traditional medicinal and traditional scientific systems.

[59]Quinn, G. (2009, 30 November). US Patent Office to Reject Based on Traditional Knowledge. *IPWatchdog*. www.ipwatchdog.com/2009/11/30/us-patent-office-to-reject-based-on-traditional-knowledge/id=7502

[60]Lemley, M. A., & Sampat, B. (2012). Examiner Characteristics and Patent Office Outcomes. *The Review of Economics and Statistics, 94*(3), 817-827. www.mitpressjournals.org/doi/abs/10.1162/REST_a_00194?journalCode=rest

[61]Sampat, B. (2010). When do Applicants Search for Prior Art? *The Journal of Law and Economics, 53*(2), 399-416. www.journals.uchicago.edu/doi/abs/10.1086/651959?journalCode=jle

[62]Swiderska, K. (2006). Op. cit.

[63]www.csir.res.in/external/heads/outputs/PatentPortfolio.htm

[64]genecampaign.org/about-us

[65]Menon, R. (2007, 13 January). Traditional knowledge receives a boost. *India Together*. indiatogether.org/tkdl-economy

- *Navdanya:* Navdanya, a similar initiative, is a network of seed keepers and organic producers spread across 17 states in India. It was set up by Dr. Vandana Shiva. Shiva has helped start 111 community seed banks across the country, and trained over 400,000 farmers in organic farming and biodiversity conservation over the past two decades.[66] Central to Shiva's work is the idea of seed freedom, or the rejection of corporate patents on seeds. She has campaigned against the implementation of the WTO's 1994 Trade Related Intellectual Property Rights (TRIPS) agreement, which broadens the scope of patents to include life forms.

  In 2005, Shiva's organisation was one of the three organisations that won a 10-year battle in the European Patent Office against the biopiracy of neem by the US Department of Agriculture and the corporation WR Grace, mentioned above. In 1998, Navdanya began a campaign against the biopiracy of basmati rice by US corporation RiceTec Inc. In 2001, following intensive campaigning, RiceTec lost most of its claims to the patent.

8. Nodes of engagement

In order to create a roadmap to increased efficacy for the TKDL and other strategies following its model, it is necessary to make certain alterations to the manner in which the database is structured, presented and operated.

- *Government:* According to a report from the UN Rapporteur on the rights of indigenous people,[67] one of the main obstacles to realising rights for these communities is their recognition by government. The report notes that there is a general reluctance to recognise these communities, which means that governments usually exclude such communities from international standards of protection that would promote the rights of such people.
- *Civil society and wider communities:* TK systems require all the external support they can get in order to protect their mandate. Civil society must engage effectively with the TKDL initiative, encourage the accuracy of its records through research, and stimulate dialogue regarding key issues mentioned above. As pointed out by the UN Special Rapporteur on the rights of indigenous people: "Much more needs to be done to understand fully how … treaties and agreements can undermine or reinforce indigenous peoples' rights and how they shape the trajectories of national economic development plans."[68]

[66] www.navdanya.org/about-us

[67] Human Rights Council. (2014). Report of the Special Rapporteur on the rights of indigenous people, Victoria Tauli-Corpuz. unsr.vtaulicorpuz.org/site/index.php/documents/annual-reports/26-annual-report-hrc-2014

[68] Ibid.