Max Planck Institute for Innovation and Competition Research Paper No. 21-23

Reto M. Hilty, Pedro Henrique D. Batista and Suelen Carls

Traditional Knowledge, Databases and Prior Art – Options for an Effective Defensive Use of TK against Undue Patent Granting

Max Planck Institute for Innovation and Competition Research Paper Series

Traditional Knowledge, Databases and Prior Art – Options for an Effective Defensive Use of TK against Undue Patent Granting

Prof. Dr. Reto M. Hilty[1], *Pedro Henrique D. Batista*[2] *and Dr. Suelen Carls*[3]

I. INTRODUCTION

In the past few decades, the international community has witnessed intense discussions on patenting inventions based on traditional knowledge (TK) from indigenous and local communities,[4] especially those related to biological and genetic resources. Several alternatives have been considered to avoid this aspect of so-called *biopiracy*[5] and protect those communities' interests, including the defensive use of TK against attempts to patent inventions that do not fulfil the patentability requirements. Since information included in the prior art can harm the novelty and even the inventive step (or non-obviousness) of an innovation, its consideration by patent offices could suffice to achieve the objective of defensive protection.

Another defensive strategy is the use of databases. Although they are not mandatory for placing TKs in the prior art, since the early 2000s, countries with a pronounced cultural heritage have established databases with written and systematised information on TK.[6] They aim to facilitate the identification of the previous existence of this knowledge during the patent examination. The Indian Traditional Knowledge Digital Library (TKDL) is one significant example of this. Individual agreements between governments owning such databases and patent offices regulate the use of the indexed information they contain. The number of such agreements, usually with patent offices

[1] Director, Max-Planck-Institute for Innovation and Competition (Munich).
[2] LL.M. (Munich). Research Fellow and Doctoral Student, Max-Planck-Institute for Innovation and Competition (Munich).
[3] Senior Research Fellow, Max-Planck-Institute for Innovation and Competition (Munich).
[4] With due recognition of the important discussion on the classification of indigenous and local populations as peoples for the purpose of attributing rights in international law, this article, which deals with traditional knowledge associated with genetic resources, uses the term communities, as envisaged by the Convention on Biological Diversity and in the Nagoya Protocol. On this topic, see: Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* (Brill 2014) 32.
[5] Sangeeta Udgaonkar, 'The Recording of Traditional Knowledge: Will It Prevent "Bio-Piracy"?' (2002) 82 Current Science 414; John Reid, 'Biopiracy: The Struggle for Traditional Knowledge Rights' (2009) 34 American Indian Law Review 78.
[6] See, for instance: Udgaonkar (n 2) 413.

located in developed countries and at zero cost, has increased over the past ten years.[7]

However, the effectiveness of the defensive use of TK depends on two factors. First, it is essential to know if the TK is publicly accessible and, therefore, covered by the prior art. Second, regarding databases, it is important to know how likely it is that the information they contain will prevent the patenting of an invention. In this regard, a relevant question is whether the TK in the databases is in fact a part of the prior art. A presumption in this case is not advisable because part of that knowledge might not be publicly accessible, e.g., when a local or indigenous community holding the TK has neither shared it nor is willing to share it with a random number of third parties.

Against this background, this chapter's objective is to analyse in more depth under which conditions TK can be considered as part of prior art and thus contribute to the defensive use of cultural heritage to avoid the undue patenting of inventions based on it. To this end, it mainly examines the public accessibility of information and the specific configuration of the TK databases. Further, the option of extending the relevant prior art to include TK that is not publicly accessible, but only available within the relevant communities, will be addressed to determine its effectiveness as well as its compatibility with the international patent law. After addressing those questions, it will be possible to point out potential gaps in the defensive use of TK and make recommendations that can improve its effectiveness, which can also be useful both for existing databases and for that established in the future.

In line with that, section II starts by dealing with the definition of prior art in patent law. Section III addresses the accessibility of TK inside the communities, including the different forms of access, the granting competence and the use conditions. Section IV focuses on the accessibility of TK in the most relevant international databases and the respective access conditions and points out possible consequences for patenting inventions based on the knowledge in the databases. Section V deals with the effectivity of the extension of the concept of prior art to TK that is not publicly accessible as well as with the compatibility of such measure with the patent law. Finally, section VI presents recommendations for an adequate treatment of traditional knowledge and the respective databases commensurate with their objectives.

[7] The official TKDL official website informs that currently there are lists 13 access agreements currently in force. For details, see: 'About TKDL' <http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng> accessed 17 May 2021.

II. THE PRIOR ART IN PATENT LAW

Article 27.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides that 'patents shall be available for any inventions (…), provided that they are *new*, involve an *inventive step* and are capable of *industrial application*.' However, there is no definition for each of these patentability requirements in this agreement, which leaves the countries and regional blocs with considerable flexibility to define them.[8] Despite this lack of binding understandings in TRIPS, the novelty of an invention is usually associated with the fact that it is not a part of the prior art.[9] This is confirmed by the references to the prior art in the Patent Cooperation Treaty (PCT),[10] although even this international treaty makes clear that any Contracting State is free to apply the criteria of its national law in respect of prior art.[11] Given that the concept of inventive step also takes the obviousness of the invention to a person skilled in the art into account, the prior art observation may also be a relevant starting point for verifying such patentability requirement.

The prevalent understanding in legal scholarship is that prior art does not comprise all existing information or knowledge, but only that which is publicly accessible at the legally relevant time of its consideration,[12] which may be the date of patent filing or of patent priority.[13] This is the case when the information is accessible to a group of people whose size and randomness of its composition is not controlled by the inventor[14] and, therefore, also available to an undetermined number of experts. It is noteworthy that the determinant element of the prior art is the accessibility of information and the *possibility* of access to it. It is not a requirement, though, that a certain

[8] Reto M Hilty and Matthias Lamping, 'Declaration on Patent Protection – Regulatory Sovereignty under TRIPS' (2016) 14. Recital 3.1, 3.2.
[9] See, for instance: UNCTAD, 'Dispute Settlement' (2003) <www.unctad.org> accessed June 7, 2021. 24.
[10] See Arts. 15, 16, and 33 PCT.
[11] Art. 27(5) PCT. See also: Brice C Lynch, 'International Patent Harmonization: Creating a Binding Prior Art Search within the Patent Cooperation Treaty Note' (2012) 44 George Washington International Law Review 403, 421.
[12] ibid 418; Virgil E. Woodcock, 'What Is Prior Art' (1958) 3 Vll. L. Rev. 255, 268; Udgaonkar (n 2) 414; World Intellectual Property Organization, 'The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit' (2012).
[13] Justin Malbon, Charles Lawson and Mark Davison, The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary (Edward Elgar 2014) 419. Recital 27.24; Philip M Webber, 'Priority Patent Applications' (2005) 4 Nature Reviews Drug Discovery 877. Malbon, Lawson and Davison; Webber.
[14] Rudolf Kraßer and Christoph Ann, *Patentrecht: Lehrbuch zum deutschen und europäischen Patentrecht und Gebrauchsmusterrecht* (CH Beck 2016), 281; Klaus-Jürgen Mellulis, 'Art. 54 – Neuheit' in Georg Benkard and others (eds), *Europäisches Patentübereinkommen*, vol 4 (CH Beck 2018), Recital 49.

number of people in fact access it.[15] Thus, the capacity of technical use of the information by the people who have accessed it is also irrelevant for analysing the prior art.[16]

Based on this definition, information accessed by a small and controllable number of people following a legal or contractual - tacitly or expressly - duty of confidentiality is not understood as being in the prior art because it is not accessible by the public.[17] Even in the event of a confidentiality breach or information misuse by third parties, the information will only be part of the prior art if it is accessible to third parties in good faith from whom further diffusion can be expected.[18]

Nevertheless, it is important to note that the prior art determination may depend on how and where the information is accessible according to national law. The former legislation in the USA, one of the most sought-after countries for filing patents, is an example.[19] In the wording of 35 USC § 102 of the Patent Act from 1952, the prior art comprised information and knowledge that was 'known and used by others in this country [i.e., the USA], or was patented or described in a printed publication in this [i.e., USA] or a foreign country.' According to that provision, foreign information fell under the prior art only when it was described in patents documentation or printed publications.[20] Information transmitted orally, e.g., in a class or lecture, or only accessible through public use or common public knowledge, was not considered in the assessment of patentability requirements.

This differentiation is no longer in place since the entry into force of the Leahy-Smith America Invents Act (AIA) in 2013, which modified the content of § 102. Subsequently, any public disclosure - including public use, sales and other forms of availability - anywhere in the world and in any language, is part of the prior art.[21] However, this does not prevent other countries or institutions of international patent law from establishing criteria for prior art that take the form and place of accessibility of the information or knowledge into account. In this

[15] Mora Rodríguez, 'Engineering the Patent System in the Global ICT Market: A Critical Analysis' (2011); Peter Mes, *Patentgesetz, Gebrauchsmustergesetz: Kommentar* (CH Beck 2020) § 3. Recital 49.
[16] Donald Chisum, 'Sources of Prior Art in Patent Law' (1976) 52 Washington Law Review 1, 5.
[17] See: Woodcock (n 9) 274; Mes (n 12). Recital 20; Mellulis (n 11) Recital 172.
[18] Woodcock (n 9) 274; Mes (n 12) Recital 20; Kraßer and Ann (n 11) 284; Mellulis (n 11) Recital 172.
[19] Kraßer and Ann (n 11) 285; Mellulis (n 11) Recital 49.
[20] Chisum (n 13) 5.
[21] Robert P Merges, 'Priority and Novelty Under the AIA' (2012) 27 Berkeley Technology Law Journal 1023, 1020; Dylan O Adams, 'Patents Demystified: An Insider's Guide to Protecting Ideas and Inventions' (American Bar Association 2015) 67; Rebecca Goldman Rudich, 'Novelty and Grace under the AIA' in John M White (ed), *Patent Eligibility, Prior Art and Obviousness 2017: Current Trends in Sections 101, 102 and 103* (Practising Law Institute 2017) 41.

regard, it is noteworthy that the relevant prior art for international search within the scope of the PCT consist of 'everything which has been made available to the public anywhere in the world by means of *written disclosure*'.[22] Written disclosure is also required for the assessment of the prior art for the purposes of the PCT international preliminary examination.[23] Despite this, Art. 27 (5) PCT ensures the freedom of the Contracting States to apply their own criteria in respect of prior art during the national phase of the patent examination.[24]

In any case, the current U.S. law comes close to the concept of prior art adopted in the European Patent Convention (EPC). According to Art. 54 EPC, '[T]he state of the art shall be held to comprise 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.' Thus, the prior art comprehends not only patent documents, printed publications or further information disclosed in written form, but also information available by public use or in any other way, and there are no restrictions related to the geographical location, the language or the way the relevant information became available to the public. [25]

However, it is important to highlight that the prior art available to the examiner consists mainly of the documents listed in the search report, which contain a written description of the information.[26] Likewise, patent office examiners from different countries are not expected to know all languages. For that reason, a written description has higher chances to be considered by patent examiners, especially if presented in a widely used language, such as English.[27] Actually, this restriction in the patent prosecution does not prevent non-written information from being considered in further phases, e.g., during an opposition or nullity action. Still, the burden of the proof is likely to be

[22] World Intellectual Property Organization, Regulations under the Patent Cooperation Treaty, as in force from July 1, 2020 Rule 33.1.
[23] ibid.
[24] PCT. Art. 27 (5): 'Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.'
[25] See: European Patent Office, 'Guidelines for Examination'.Especially Chapter IV – State of the art. – 1. General remarks and definition. See also: Horst-Peter Götting, 'Biodiversität und Patentrecht' (2004) GRUR Int. 735.
[26] Götting (n 22) 735.
[27] This information results from an interview with the German Patent and Trademark Office (Deutsches Patent- und Markenamt) in March 2021.

heavier for the interested party to prove that the information belongs to the prior art.

III. THE ACCESSIBILITY OF TRADITIONAL KNOWLEDGE

The use of that TK for patent hindrance requires that the knowledge be in the prior art. The mere fact that the information consists of a TK and belongs to a particular community is not sufficient for that.[28] The determining criterion is the public accessibility of knowledge.[29] In its Report on the Status of Traditional Knowledge as Prior Art from 2001,[30] the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO/GRTKF) accurately states that "the term 'prior art' generally refers to the entire body of knowledge that is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for specific industrial property titles, principally patents, utility models, and industrial designs."[31] There are different ways to fulfil the criteria, as detailed below.

1. Communities

First, TK may be under prior art coverage if it is publicly accessible in the indigenous or local community that owns it. In this case, third parties do not need to have previously accessed knowledge. Regardless of how evidence can be provided in specific cases, the TK is in the prior art when there is an express or tacit willingness of the community to share it in writing or oral form upon a third-party request.[32] This practice usually follows the understanding of knowledge as a universal good or right, over which there are no property rights.[33] Because of that, the knowledge becomes publicly available. The TK status as prior art is not affected even if it becomes available to an undetermined number of people under certain conditions, such as the obligation to share benefits

[28] Kraßer and Ann (n 11) 287.
[29] See Section II above.
[30] World Intellectual Property Organization, 'Report on the Status of Traditional Knowledge as Prior Art (WIPO/GRTKF/IC/2/6)' (2001) 3.
[31] World Intellectual Property Organization, 'Introduction to Intellectual Property: Theory and Practice' (Kluwer Law International BV 2008) 125.
[32] Kraßer and Ann (n 11) 287.
[33] For a discussion on the relation between TK and property rights, see: John T Cross, 'Property Rights and Traditional Knowledge' (2010) 13 Potchefstroom Electronic Law Journal (PELJ) 12.

arising from its use according to Convention on Biological Diversity (CBD)[34] and its Nagoya Protocol.[35]

However, other communities may not want to share their knowledge or only do so under secrecy.[36] This happens, for example, when knowledge is considered sacred, unique or of special cultural value to the community.[37] Furthermore, in view of its rights to grant a prior informed consent for TK access and to an equitable sharing of the benefits derived from its use,[38] the community may want to restrict access to its TK to better control the information flow and avoid its diffusion to a random number of third parties.[39] In those instances, if the knowledge is only available to community members or selected persons under the duty of confidentiality but not available to the public, it is not included in the prior art.[40]

An example of communities unwilling to share their knowledge is the Canadian Kaska communities from northern British Columbia and the Yukon. For them, a TK is a holy trust that each family passes along, and whoever becomes aware of that TK is seen as an individual who will protect the community interests. Outsiders providing services for and in the communities, as a rule, do not need to be aware of the community's TK to do their job. However, some of them can be 'fortunate enough to be offered teachings'. If that is the case:

> it is crucial to find out what the protocols are around carrying that traditional knowledge, including whether there is permission to share it with anyone else or write it down. The best practice would be to respect it, show your respect to the person who offered the knowledge and hold it confidential. If you would like to write it down, make sure permission is sought and granted before doing so.[41]

[34] Convention on Biological Diversity (CBD) 1992.
[35] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity 2011.
[36] Reto M Hilty. Rationales for the Legal Protection of Intangible Goods and Cultural Heritage, (2009) International Review of Intellectual Property and Competition Law (IIC) 894.
[37] In this respect and for the example of the Kaska community, see: World Intellectual Property Organization, 'The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit' (n 9).
[38] Convention on Biological Diversity (CBD) Art. 8 (j); Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (n 32) Art. 7.
[39] Reid (n 2) 92.
[40] World Intellectual Property Organization, 'Report on the Status of Traditional Knowledge as Prior Art (WIPO/GRTKF/IC/2/6)' (n 27) 5.
[41] Council of Yukon First Nations, 'Cultural Orientation and Protocols Toolkit Council of Yukon First Nations' (2010)

The recommendation to keep the TK confidential is part of the Cultural Orientation and Protocols Toolkit Council of Yukon First Nations. If it is duly observed by the community members and third parties who exceptionally access it, the TK remains unavailable to the public and will not constitute prior art. In those cases, however, the defensive use of the TK is not possible. Third parties who achieve the knowledge and the corresponding technical solutions independently and in good faith[42] will be able to patent inventions based on it.

Another important aspect regarding access to TK is the internal competence in the communities to grant it. While some communities do not have any form of hierarchy, others may have formal rules that establish competence. These rules can be particularly relevant if the community chooses not to share knowledge or only share it under certain conditions, such as maintaining confidentiality and benefit-sharing.

Two examples of communities with competence rules regarding the control of the TK diffusion can be found in Kenya.

Mijikenda is a traditional community consisting of nine sub-communities. Each community has its settlement and a political institution called *kaya*, administered by a council of elders, called *kambi* or *ngambi*.[43] The *Mijikenda* community is split into three counties, and seven of their sub-communities are located in *Kilifi* County, which is also the county with the highest number of *kayas* listed as world heritage.[44] The *Mijikenda* elders (*kaya* elders) have custody rights and obligations over TK. They decide on the access, use and control of the TK according to customary laws (including rites and taboos) and apply those laws. The access to the forests (who, when, and why), for instance, is defined in secrets, oral agreements and taboos. The transmission of healing knowledge is also regulated by the elders *kambi* using a rating process that considers the personal conduct and motivation of the request.[45] An individual healer can also choose a family member or friend as a helper, meaning that the helper would have access to TK. In this situation, a payment of a predetermined fee (*kadzama*) is requested from the apprentice.[46]

<http://lss.yukonschools.ca/uploads/4/5/5/0/45508033/part_7_lfn.pdf> accessed 14 May, 2021. 12.

[42] The legal consequences of a patent applicant's misconduct regarding the access and use of TK is discussed below in this section.

[43] Paul Ongugo and others, 'Protecting Traditional Health Knowledge in Kenya: The Role of Customary Laws and Practices' (2012) 14; Francis Kariuki, 'Protecting Traditional Knowledge in Kenya: Traditional Justice Systems as Appropriate Sui Generis Systems', *WIPO-WTO Colloquium Papers* (2019). 96-97.

[44] UNESCO World Heritage Centre, 'WHC-08/32.COM/24Rev: 32nd Session of the World Heritage Committee' (2008). 190-191.

[45] Ongugo and others (n 40) 14.

[46] Ibid; Kariuki (n 40) 97.

In the *Meru* or *Amîîrú* community, the decisions on the access of the TK are up to the *Njuri Ncheke*, the supreme governing body constituted by elders. Those elders have custody of the community's TK, culture, customs and traditions. They perform their duties by following a custom and practices system that includes community sanctions and oaths to govern the disclosure of TK. Moreover, the *Njuri Ncheke*, mature men of the community believed to hold the highest moral standards and have almost no faults, are the ultimate custodians of the community's TK, and it is up to them to apply the customary laws for access to it.[47]

Granting access to a small and controllable number of persons under a duty of secrecy is not enough to insert a TK in the prior art. Moreover, in practice, some communities may desire secrecy. Against this backdrop, one may ask what happens if this knowledge is improperly acquired or made publicly available due to misconduct of a third party. This may be the case when someone, despite knowing the community internal competence rules for granting TK access, intentionally obtains the TK through a community member not authorised to share it or when someone who has obtained access to information under the duty of confidentiality makes it publicly accessible.

In these cases, if TK is not accessed by *bona fide* third parties from whom further dissemination can be expected or does not become accessible to a large and random number of third parties, it will not be publicly available.[48] Otherwise, it will be understood as in the prior art for the purposes of the patent law.

Moreover, the information unduly available in the prior art can harm the interests of an inventor (or a person authorised by him) in obtaining a patent. For that reason, when defining novelty, most countries' laws exclude abusive disclosure or disclosure after a breach of trust from the prior art if it occurs within a given time before the filing date.[49] This rule, however, does not prevent TK from becoming part of the prior art, even against the will of the harmed community, since the publication of the patent application makes the information invariably publicly accessible.

The discussion on the adequacy of the *offensive* use of the patent through the attribution of exclusivity rights to indigenous and local communities and the legal possibility of these communities to be holders of patent rights is beyond the scope of this article.

[47] Kariuki (n 40) 97.
[48] Kraßer and Ann (n 11) 285; Mellulis (n 11) Recital 174.
[49] See WIPO's comparative table on the grace period in national and regional laws: World Intellectual Property Organization, 'Certain Aspects of National/Regional Patent Laws – Grace Period' (2020).

2. Public Knowledge, Public Use or Offer for Sale

As a rule, when the TK is publicly used or applied by people outside the rights-holding community or incorporated into products that put into the market, it becomes part of the prior art. A good example is traditional Chinese medicine, whose elements, though not always assigned to a specific community, are often part of the structure of knowledge accessible to the public in China and other countries and are frequently used in medicines and services.[50]

Another well-known example refers to the knowledge of specific properties of the oil of the neem tree as a fungicide.[51] In September 1994, the European Patent Office (EPO) published the patent EP 0436257 B1 related to a process for combating fungi in plants by fungicides having in their composition a percentage of oil extracted from neem tree leaves. This technique has made it possible, *inter alia*, to eliminate fungi and protect plants from fungicidal infection. However, the effects of oil fungicides have been proven as a subject of extensive traditional knowledge and applied in various sectors of Indian society. After the long process of opposition filed by the Parliament's Green Group, the EPO acknowledged that the knowledge was part of the prior art and concluded that the requirements of novelty and inventive step had not been adequately met. As a result, the patent was revoked. The appeal after the opposition has failed.[52]

3. Publications

Among the different forms of accessibility of information, one of the most relevant pieces of evidence of prior art is the publications. That is due to possible legal and factual limitations related to the concept of the prior art. As explained above, some countries and institutions of international patent law may determine that prior art covers only printed publications or written information. The defensive use of TK is intended to prevent undue patenting not only in the country of origin of the rights-holding community, but also abroad. For this purpose, the expression of the knowledge in a printed publication may be sufficient to avoid potential limitations to the recognition as prior art and, hence, to reach the objective of the communities and the national policy.

---

[50] See, for instance: Zhongdi Liu and others, 'Application of Traditional Chinese Medicine in Medical Practice: A Survey of Community Residents in Beijing, China' (2017) 37 Journal of traditional Chinese medicine = Chung i tsa chih ying wen pan 261, 106.

[51] Shubha Ghosh, 'Globalization, Patents, and Traditional Knowledge' (2003) 17 Columbia Journal of Asian Law 93.

[52] See at <https://register.epo.org/application?lng=en&number=EP90250319> details for the patent application 'EP0436257 - Method for Controlling Fungi on Plants by the Aid of a Hydrophobic Extracted Neem Oil'. See also: Christina Federle, Biopiraterie und Patentrecht (Nomos 2005) 65.

The turmeric case is an illustrative example of the relevance of print publications.[53] In September 1995, the United States Patent and Trademark Office (USPTO) granted patent No. 5,401,504 in favour of the University of Mississippi Medical Center. The invention referred to a wound healing process through the application of an effective amount of turmeric powder. The respective patent claims comprised the method of application and specifications regarding the type of wound to which to apply the medical product.[54] Turmeric is a yellowish powder extracted from the curcuma plant, originally from South Asia. In India, its use is widespread not only as a food colouring, but also in traditional medicine to treat inflammation. [55] Claiming that this traditional Indian knowledge was part of the prior art, the Council of Scientific & Industrial Research of India requested a re-examination of the patent in 1996. The following year, the USPTO rejected the patent claims because the invention lacked novelty and inventive step.[56]

The curious fact is that, under the patent law in force in the USA at that time, the information and knowledge contained in other countries were only considered part of the prior art if they were included in printed publications. As a result, the various unwritten pieces of evidence of oral transmission and diffusion of ancient knowledge about the wound-healing effects of Turmeric presented by India was of little help or not useful at all. Determinant for the rejection of the patent by the USPTO was only the 32 documents published in Sanskrit, Urdu and Hindi in which the relevant applications of Turmeric were presented.[57]

From a practical point of view, the written publication of already existing information may be relevant also for patenting in countries that do not limit prior art to printed publications. As indicated above, patent examiners usually base their search on written documents available for their search.[58] Thus, the written publication of traditional knowledge in a language accessible to examiners worldwide, such as English, may facilitate the prompt and *ex officio* consideration of TK in the prior art in the context of patent prosecution.

The form in which TKs are published may vary. The patent offices commonly consider the publication of patent-related documents.[59] Thus, when TK is the subject of or has been described in a patent already granted or even a patent application already published, it becomes publicly accessible and may prevent the patenting of future

[53] Ghosh (n 48) 93.
[54] Federle (n 49) 63.
[55] ibid 96.
[56] The USPTO documents related to 'Use of Turmeric in Wound Healing' application are available at: < 14996638657526481111-05401504 (storage.googleapis.com)>.
[57] Tejaswini Apte, 'A Simple Guide to Intellectual Property Rights, Biodiversity and Traditional Knowledge | Publications Library' (2006) 63.
[58] See section II above.
[59] Adams (n 18) 68.

inventions that may use it. In addition, TK publication for these purposes may occur through books, magazines and other literature sources and – at least regarding countries that do not require a printed publication – also on the Internet or any other kind of recording.[60] In some countries, there are even journals specialised in publishing articles that describe traditional knowledge and its use in technical areas. The Korean Journal of Traditional Knowledge managed by the Korean Intellectual Property Office is one example. In addition, the Korean Rural Development Administration periodically publishes books with this content.[61] The Indian Journal of Traditional Knowledge[62] has the same purpose, while the Journal of Traditional Chinese Medicine promotes the publication of current scientific, technical studies related to the country's ancient medicinal knowledge.[63]

Finally, it is imperative to note that documenting TK does not necessarily mean placing it in the prior art. Documents restricted to a small number of people or a group of people who share a duty of confidentiality are not considered publicly accessible. The acquisition of prior art status, therefore, depends on the availability of these documents.[64] However, being publicly available does not imply that the knowledge is widely or easily accessible to all people. For example, TK can be under prior art even if the documents in which it is described are in special libraries or museums with access to a restricted group of people, if this group is random and is not obliged to maintain confidentiality by force of law or contract.

V. TRADITIONAL KNOWLEDGE DATABASES

As noted, the identification of TK by patent offices can be challenging, even when it belongs to the prior art. In practice, the examiners are unaware of the information used and transmitted orally abroad. Likewise, publications, especially when written in an unknown language or not easily and systematically recoverable by the examiners, may eventually be disregarded — the mentioned cases of neem and turmeric demonstrate these shortcomings.[65] In that context, databases

[60] World Intellectual Property Organization, Documenting Traditional Knowledge – A Toolkit (2017). 14. See also: Adams (n 18) 67; Mes (n 12) Recital 25.
[61] Jin-Seop Shin, Yu-Seon Lee and Myung-Sun Lee, 'Protection and Utilization of Traditional Knowledge Resources through Korean Traditional Knowledge Portal (KTKP)' (2010) 10 The Journal of the Korea Contents Association 422.
[62] Further information at: 'Indian Journal of Traditional Knowledge (IJTK)' <http://op.niscair.res.in/index.php/IJTK> accessed 8 June 2021.
[63] Further information at: 'Journal TCM: Journal of Traditional Chinese Medicine' <http://www.journaltcm.com/> accessed 8 June 2021.
[64] Mes (n 12) Recital 27.
[65] Wend B Wendland, 'Intellectual Property, Traditional Knowledge and Folklore: WIPO's Exploratory Program', (2002) IIC 503.

compiling the TK can play a relevant role in patent examination.[66] However, to facilitate the defensive use of TK, the databases must have specific characteristics regarding the public nature and accessibility of the information contained therein.

(1) Definition of Databases

The TK documentation process consists of identifying, collecting, organising, and registering or recording the knowledge in a platform to maintain, manage, use, disseminate, or dynamically protect it.[67] The denomination of the result of this documentation, however, is not uniform. Although the term *database* is commonplace in the field of TK, the scholarship, the different national laws and regulations, and international organisations' documents offer different terms, such as records, inventories, catalogues, or networks.

The Secretariat of the Convention on Biological Diversity's points out that, while the WIPO/GRTKF usually refers to *traditional knowledge registers* (TKRs) as (i) legal registers created by law; and (ii) non-statutory databases developed to address a legal issue, there is also a distinction between TKRs, *community traditional knowledge databases* (CTKDBs), and *external traditional knowledge databases* (ETKDBs) for illustration purposes.[68]

TKRs are legal collections established by law. They can serve as sources for prior art search or protect TK under trade secrets law and *sui generis* intellectual property law. Moreover, the act of registration in a TKR can have a constitutive or a declaratory effect regarding TK-related rights.[69] Constitutive TKRs can grant certain rights to communities provided they meet the requirements, including registration. Declaratory TKRs recognise the existence of prior rights.

The ETKDBs serve primarily as a source of prior art, but they are neither directly organised nor controlled by the communities. Governments, museums, corporations, non-governmental organisations (NGOs), and inter-governmental organisations (IGOs) can be behind their establishment. In turn, CTKDBs are compilations of TK organised and managed by the communities or organisations on their request and behalf. They serve the community's internal use and focus on

[66] Udgaonkar (n 2) 416; Maria Luiza Grabner, 'Conhecimentos Tradicionais: Proteção Jurídica e Diálogo Intercultural' (USP 2009) 133. Viviane Alves Bertogna, 'Biodiversidade e Propriedade Intelectual No Brasil' (FADUSP 2003). 170.
[67] World Intellectual Property Organization, 'The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit' (n 9).
[68] Secretariat of the Convention on Biological Diversity, 'Composite Report on the Status and Trends Concerning the Knowledge, Innovations and Practices of Indigenous and Local Communities (UNEP/CBD/WG8J/4/INF/9)' (2006).
[69] Susette Biber-Klemm and Thomas Cottier, Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives (CABI Pub 2006) 228.

protecting, preserving, and promoting traditional knowledge and cultural heritage. Secondary functions may include documentation for land demarcation, treaty negotiations, or traditional resource claims.[70]

Other than the previous organisations, the Asian Group and China suggested in a position paper a differentiation between TK registers and TK databases based on the prior art. According to them, States might, 'as appropriate, compile databases of traditional knowledge which is in the public domain [understood as the information in the prior art according to the definition presented in this chapter] and make these databases available to patent-granting authorities for the purposes of prior art searches, to prevent the grant of any intellectual property rights over such public domain knowledge.'[71] Moreover, they may 'establish registers of traditional knowledge elements which are not in the public domain and keep the contents of the registers undisclosed, pending the possible establishment of new protection standards for the traditional knowledge elements contained in the registers.'[72]

The variety of denominations might be contradictory or at least confusing. The acknowledgement of the TK legal status for purposes other than the determination of prior art[73] is irrelevant to the analysis of the defensive use of TK. Moreover, using different, non-unified terms to characterise a dataset in terms of availability to third parties or the publicity of the information contained therein may bring about undesired complications, especially when working with country examples that use different nomenclatures for similar instruments. For practicality's sake and because a more accurate definition is unnecessary, this chapter opts to use the term TK database in a broad sense to refer to any result of the structured and schematised compilation of TK descriptions, regardless of a particular function or the characteristics of the information contained therein. Those may include digital libraries, networks, registries or even databases to define this compilation of TK.

2. Databases and Prior Art

The existence of a TK database is not enough to guarantee the defensive use of the knowledge contained therein. The effective use of a database depends on its structure and organisation. The reason is that databases do not necessarily guarantee that the knowledge contained therein is publicly accessible. A database that only comprises information about

[70] Secretariat of the Convention on Biological Diversity (n 65) 11.
[71] World Intellectual Property Organization, 'Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources (WIPO/GRTKF/IC/4/14)' (2002) 2.
[72] World Intellectual Property Organization, 'Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources (WIPO/GRTKF/IC/4/14)' (n 68) 2.
[73] Such as, for example, to be the subject of prior informed consent or mutually agreed terms under the CBD and the Nagoya Protocol or for other state programmes.

the genetic and biological resources used by communities, but does not include descriptions of the knowledge, its use, and its application for a particular technical purpose, is not in itself sufficient to make the TK in question part of the prior art. The same is true of a database that, although describing existing TK, is not available to the public, but only to a restricted group of people under a duty of confidentiality, e.g., patent offices. In these cases, the TK contained therein will only belong to prior art if it is publicly accessible in a manner independent of the database, as in community access, public use or publications.

Therefore, to verify the capability of a database to prevent undue patenting of inventions based on the TK contained therein, it is necessary to ascertain the degree of its accessibility to third parties and the relevance of the information contained therein to the prior art. In the following, open and restricted databases will be analysed in view of their potential to influence patent examinations. While some TK databases adopt a mixed form concerning documented content and access to registered data, others adopt a uniform treatment.[74] Some of the latter will be mentioned as examples in the analysis below.

In this context, two aspects should be highlighted. First, since for patent law purposes the verification of prior art is primarily a factual issue, the specific configuration of TK databases may prevent the patenting of inventions, even if this is not their primary or the intended purpose. Second, suppose a TK database goal is to influence the novelty and inventive step of an invention exam. In that case, it is essential that patent examiners have (i) knowledge of its existence, (ii) access to it and (iii) the ability to deal with it and work with information contained in it. Contact with the patent offices and WIPO[75] for dissemination and availability purposes and the use of a globally accessible language can facilitate the realisation of this goal.

(a) Open databases

Open databases offer free access to the TK described therein to an unrestricted number of people. An example is the Korean Traditional Knowledge Portal (KTKP). Maintained by the Korean Intellectual Property Office (KIPO) since 2004, it consists of a centralised national TK repository.[76] Based on Korean traditional literature and scholarly

[74] For the decentralised Indian People's Biodiversity Register, see: National Biodiversity Authority, 'People's Biodiversity Register' (2013) <www.nbaindia.org> accessed 8 June 2021. For the Venezuelan Biozulua, see: Alejandro Argumedo and others, 'The Role of Registers and Databases in the Protection of Traditional Knowledge: A Comparative Analysis' United Nations University Institute of Advanced Studies (2004). 16.

[75] See for instance: World Intellectual Property Organization, 'Draft Quick-Win Online Databases and Registries of Traditional Knowledge and Genetic Resources' (2016).

[76] 'KTKP: Korean Traditional Knowledge Portal' <https://www.koreantk.com/ktkp2014/> accessed 14 May 2021.

articles, there is documented information on traditional and local food, literature techniques and other intangible cultural heritage elements, and TK descriptions related to agriculture and medicine. For example, in traditional medicines and cures, detailed technical information on their properties, dosage, application, efficacy, and contraindications are usually provided. Similarly, there are references to the date of the TK publication in the database. Although that might differ from the date the TK became part of the prior art,[77] it is in most cases sufficient for the determination of the scope of the prior art by the patent examiner. The KTKP targets defensive TK protection and aims to promote TK-related studies and industries.[78]

For purposes of defensive use, open databases with a detailed description of knowledge have the advantage of not relying on the independent public accessibility of such knowledge. Even knowledge not accessible by other means such as publications or public use become publicly accessible from the moment they are published in an open database. Therefore, patent examiners consider that TKDB content a source of the prior art when analysing novelty and inventive steps related to an invention. In addition, the database content can be helpful to courts when analysing a nullity action against a patent already granted for an invention based on TK.

(b) Restricted databases

Despite the advantages of open databases for TK defensive use against patents, countries and communities interested in the compilation of their TK may choose not to adopt them because they have a primary interest in maintaining the confidentiality of TK. This is the case, for instance, when the documentation and collection of this knowledge is aimed to serve only community members or third parties under a confidentiality regime. In such cases, the establishment of the database pursues only internal purposes or public policies unrelated to patents, but not the defensive use of TK.

The approach of Canada's Kaska communities is on the restrictive side[79] where there is no interest in sharing their TK with third parties. Despite that, the *Kaska Traditional Knowledge Networ*k was developed by them in partnership with the ICT Development Group to administer and share TK among the several *Kaska Dena Nation* communities from northern British Columbia and the Yukon. The TK documentation employs modern technology, including a web-based portal, TK directory and geospatial data applications. The TK is usually

[77] For instance, when the TK was already publicly available in a period before publication in the database.
[78] Lakshmi Poorna, Mymoon Moghul and Hariharan Arunachalam, 'Preservation and Protection of Traditional Knowledge – Diverse Documentation Initiatives across the Globe' (2014) 107 Current Science 1242-1243.
[79] See section III.1. above.

recorded in video format.[80] Another Canadian example and one of the most ambitious documenting projects led by a community itself is the *Traditional Knowledge Databases of Inuit of Nunavik*. The project aims 'to create a dialogue based on respect and equality, not to create a catalogue and make it available to the real scientists.'[81] Thus, it remains a restricted database. A reason for that is the lack of a Canadian protection regime for TK and, therefore, the lack of originality of the recorded information, which has no legal rights under existing law. In Peru, the National Confidential Register administered by the National Institute for the Protection of Competition and Intellectual Property (INDECOPI[82]) stores TK that indigenous peoples wish to keep confidential.[83]

Since access to the database is restricted, its use alone is not enough to place the knowledge in the prior art. This does not mean that all information contained therein is excluded from the prior art. Information accessible to the public, regardless of the database, will remain part of the prior art and may eventually be considered in the context of a patent proceeding or a nullity action.

In addition, there are also cases in which databases are created to specifically compile TKs already included in the prior art for their defensive use but still have restricted access. A significant function of the restriction is to prevent information from being available to anyone anywhere in the world.[84] On the one hand, CBD and the Nagoya Protocol guarantee indigenous and traditional communities the right to demand prior informed consent agreements before allowing TK access. On the other hand, global open access would make it even more difficult to control information and facilitate the violation of these rights by third parties interested in using traditional knowledge without obtaining the consent of the community and sharing the benefits arising from the use.[85]

Nevertheless, restricted access may be counterproductive to the purposes sought by the creators of this type of database. Without due access, patent offices cannot consider the information contained in the databases when determining the prior art. For this reason, appropriate

[80] See: 'SRISTI' <https://www.sristi.org/> accessed 8 June 2021. Kelly Bannister and Preston Hardison, 'Mobilizing Traditional Knowledge and Expertise for Decision-Making on Biodiversity' (2006). 16-17.
[81] Darrell Addison Posey, 'Indigenous Peoples and Traditional Resource Rights: A Basis for Equitable Relationships?' (1995) 19.
[82] In Spanish, Instituto Nacional de Defensa de la Competencia y la Propiedad Intelectual.
[83] Sylvia Bazán Leigh, 'A Cuatro Años de La Ley N.° 27811: Algunas Interrogantes En Torno a Su Aplicación' (2008) 4 Anuario Andino de Derechos Intelectuales. 291-302.
[84] Udgaonkar (n 2) 416.
[85] Reid (n 2) 92.

access should be granted to patent offices of interest to the country of origin or TK-holding communities. The access concession might require the commitment to secrecy so that interests outside the patent law are not harmed.[86]

The Peruvian TK National Public Register (*Registro Público Nacional*) is an example of that kind of database. Although it contains descriptions of TK of Peruvian indigenous communities that is already in the prior art, its content is not publicly accessible. The National Commission Against Biopiracy, created on May 1, 2004 and chaired by the INDECOPI, monitors patent applications and granted patents all around the world. It is responsible for sharing the specific information contained in the National Public Register with patent offices in case of patent applications related to traditional knowledge and with the authorities that are competent for the judgement of nullity actions related to such patents.[87]

Another example is the prominent Indian Traditional Knowledge Digital Library (TKDL),[88] one of the most extensive documentation projects carried out so far. The Indian government led the initiative in collaboration with other public bodies. It provides TK-related information on Indian Systems of Medicines[89] in different languages (including English)[90] in a format that follows a Traditional Knowledge Resource Classification and is understandable by patent examiners in other countries. The TKDL is not open to the public, but it is accessible by different patent offices because of respective agreements.[91] The access is only oriented to prior art search, and the content of the database cannot be disclosed to third parties.

Because of the restricted and controlled access, this type of TK database is also not *per se* sufficient to extend the knowledge contained

[86] Udgaonkar (n 2) 418.

[87] See: Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources Arts. 17, 23. See also: Kelly Sanchez, 'The Problem with the Biopiracy in Peru' (2019) China IP Magazine <http://www.chinaipmagazine.com/en/news-show.asp?id=10654> accessed 8 June 2021.

[88] CSIR, 'Traditional Knowledge Digital Library – Insomnia' Council of Scientific & Industrial Research | CSIR | GoI (June 25, 2020) <https://www.csir.res.in/documents/tkdl> accessed 23 April 2021.

[89] Ayurveda, Siddha, Unani and Yoga.

[90] English, French, German, Japanese, and Spanish. Though the codified Indian systems of medicine were publicly available in local languages such as Sanskrit, Urdu, Arabic, Persian, and Tamil, they were not accessible to patent examiners at other patent offices and could not have been understood by them even if they had been.

[91] To protect India's interest against any possible misuse, the CSIR has signed specific non-disclosure and access agreements with nine patent offices so far: IP Australia, the Canadian Intellectual Property Office, the Chilean Patent Office, the European Patent Office, the German Patent Office, the India Patent Office, the Japan Patent Office, the United Kingdom Patent and Trademark Office and the United States Patent and Trademark Office.

therein to the prior art. Since the TK description in such cases is not publicly accessible, it could be ignored during the patent prosecution or a judicial analysis, e.g., in a patent invalidity action. To better guide their users and achieve their defensive goals, these databases should expressly refer to aspects that prove that each piece of TK described belongs to the prior art.

The Indian TKDL fulfils these conditions. It has achieved relative success in preventing the patenting of inventions related to the TK described therein due to its *ex officio* consideration by the patent examiners and oppositions that expressly refer to it. Based on evidence of prior art recorded in the TKDL, several patent applications have been annulled, withdrawn or amended at no additional cost and in a few weeks or months.[92]

However, the extent of this success is uncertain, as the information found in the legal scholarship or published by patent offices varies. An EPO presentation from 2011 reports that, at that point, there were 13 cases in which a patent examiner mentioned a TKDL document.[93] Another source indicates that between July 2009 and June 2010, the TKDL team identified 36 patent applications related to Indian TK against which it filed evidence.[94] Furthermore, it is reported that:

> In two such cases EPO has already set aside its earlier intention to grant patents after it received TKDL evidence. In other eleven cases, applicants themselves decided to withdraw their 4 to 5-year old application on being confronted with TKDL evidence. It is expected that in balance 23 cases, either EPO would reject these applications or applicants themselves would withdraw their wrong claims/patent applications unless they are able to establish the novelty of their claims/applications.[95]

Mentions of TKDL in the patent examination promoted by other patent offices were reported in 2010 as follows: US (four mentions); Egypt (one mention); Germany (two mentions); South Korea (two mentions); United Kingdom (one mention); India (two mentions); China (two mentions); Taiwan (one mention); Canada (two mentions).[96]

---

[92] World Intellectual Property Organization, 'Meeting of International Authorities under the Patent Cooperation Treaty: Document Submitted by India (PCT) (PCT/MIA/22/8)' (2015) 3.

[93] Paul Schwander, 'Traditional Knowledge and TKDL at the EPO' (2011). <https://www.wipo.int/edocs/mdocs/tk/en/wipo_tkdl_del_11/wipo_tkdl_del_11_ref_t7_1.pdf> accessed 23 April 2021 18.

[94] Anand Chaudhary and Neetu Singh, 'Intellectual Property Rights and Patents in Perspective of Ayurveda' (2012) 33 AYU (An International Quarterly Journal of Research in Ayurveda) 20, 33.

[95] Chaudhary and Singh (n 91) 33.

[96] VK Gupta, 'TK Documentation and Defensive Protection: An Example from India' Intellectual Property and Sustainable Development: Documentation and Registration

V. EXTENSION OF THE PRIOR ART TO NON-PUBLICLY AVAILABLE TK

As noted above, the prior art basically comprises traditional knowledge that is publicly accessible to third parties outside the indigenous or local community that holds this knowledge. This definition is related to the concept of *novelty* in the TRIPS Agreement. Information that already exists, but is not accessible to third parties, is new from the point of view of society and experts who may eventually use it for scientific and commercial purposes. Thus, third parties who independently obtain this information may obtain patents for inventions based on it. Likewise, third parties who obtain this information directly from the community and under duty of confidentiality may, depending on the circumstances and agreed conditions between the user and communities, also hold patents related to this knowledge.[97]

This understanding, however, is not shared by all indigenous and local communities. In fact, the processes of knowledge production, appropriation and dissemination in these communities do not necessarily coincide with the pre- and post-appropriation economic dynamic established in the framework of the patent law.[98] Even the concept of *public* may vary according to customary norms.[99]

This historical and cultural context may not only be considered for the purpose of questioning the free use of TK in the public domain without any users' duties over indigenous and local communities,[100] but also for reconsidering the scope of the prior art in patent law. Some authors point out that certain communities hold that the fact that the TK has been shared only within the community for centuries is enough for it to be considered part of the public domain and, thus, prior art for patent law purposes.[101] From this, one may consider the extension of

---

of TK and Traditional Cultural Expressions (2011) <https://www.wipo.int/edocs/mdocs/tk/en/wipo_tk_mct_11/wipo_tk_mct_11_ref_t_5_1.pdf> accessed 8 June 2021. 60-63.

[97] Regarding the consequences of the misconduct by third parties after accessing the traditional knowledge, see section III.1. above.

[98] Chidi Oguamanam, 'Wandering Footloose: Traditional Knowledge and the 'Public Domain' Revisited' (2018) 21 Journal of World Intellectual Property 306, 318.

[99] ibid.

[100] See, for instance: Ruth Okediji, 'Traditional Knowledge and the Public Domain - Centre for International Governance Innovation' (2018) CIGI Paper No. 176. 16; Michael C Ogwezzy, 'Protection of Indigenous or Traditional Knowledge Under Intellectual Property Laws: An Examination of the Efficacy of Copyright Law, Trade Secret and Sui Generis Rights' (2012) 12 International and Comparative Law Review 7, 36; Jane Anderson, 'Indigenous/Traditional Knowledge and Intellectual Property' (2010) Duke University School of Law – Center for the Study of the Public Domain, 26.

[101] See, for instance: Srividhya Ragavan, 'Protection of Traditional Knowledge' (2005) 2 SSRN Electronic Journal 13; Joelle Dountio, 'The Protection of Traditional Knowledge: Challenges and Possibilities Arising from the Protection of Biodiversity in South Africa' (2011) 26 SAJAH 10, 13.

prior art to TK that is not publicly accessible to increase the effectiveness of its defensive use. In this way, the patenting of inventions based on TK could be prevented even if the inventor obtained the information independently, which would safeguard the interest of the communities in avoiding the so-called 'misappropriation' of their knowledge. This extension could be done through a redefinition of the concept of prior art or by law.

1. National Law

In general, there are no rules of international law that deal with the extension of prior art to TK that is not publicly accessible.[102] Likewise, there are no well-known legal provisions at the national level which expressly determine such extension. Despite this, some norms of national law may possibly be interpreted in this way.

An example of this is India. According to Sec. 3(p) of the Indian Patent Act, 'an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' is not an invention for the purposes of the patent law.[103] Although this provision shall not be interpreted as meaning that the use of TK precludes the patentability of inventions based on it that duly meet the patentability requirements (including those ruled in Sec. 3(d) of the Patent Act),[104] it does not make any differentiation between TK included in the prior art and TK that is not publicly available. The fact that the Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM) – the Indian Patent Office –, when dealing with the application of Section 3(p) in its respective Guidelines,[105] mentions as examples only TK that is publicly accessible in publications, could be interpreted as meaning that only this type of TK is relevant for the purposes of the patent examination.

However, Sec. 25(1)(k) and (2)(k) of the Indian Patent Act recognise as a legitimate ground to oppose the patent application the

[102] World Intellectual Property Organization, 'The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit' (n 9) 14.
[103] See: The Indian Patents Act, 1970.
[104] Hetal Patel and Sandesh Lodha, 'Case Study on Rejected Patents in India', Intellectual Property Rights - Patent (IntechOpen 2020) <https://www.intechopen.com/books/intellectual-property-rights-patent/case-study-on-rejected-patents-in-india> accessed 8 June 2021; Suchi Rai, 'Traditional Knowledge And Scope For Patent Protection - Intellectual Property - India' [2018] mondaq <https://www.mondaq.com/india/patent/668414/traditional-knowledge-and-scope-for-patent-protection?login=true> accessed 8 June 2021.
[105] See: Designs and Trademarks Office of the Controller General of Patents, 'Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material'; Designs and Trademarks Office of the Controller General of Patents, 'Guidelines for Examination of Biotechnology Applications for Patent' (2013); Designs and Trademarks Office of the Controller General of Patents, 'Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals Office of the Controller General of Patents, Designs and Trademarks' (2014).

fact 'that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available *within* any local or indigenous community in India or elsewhere'. Sec. 64(1)(q) states that this fact is also a reason for the revocation of the patent. Since the knowledge available *within* a community is not necessarily publicly accessible, there are reasons to construe Indian law as adopting an extended concept of prior art. In fact, some voices in the literature argue that TK is always encompassed by the prior art according to the Indian patent law.[106] However, there are still no clear indications from the case law that bring legal certainty to this issue.

2. Limits of the Effectiveness

In any case, those countries that might be interested in extending the concept of prior art to non-publicly accessible TK should keep in mind certain restrictions regarding the effectiveness of this tool for the TK defensive function against undue patenting.

First, the consideration of non-publicly available TK during the patent examination requires this knowledge to be accessible at least to the patent office. The creation of restricted databases containing confidential TK – such as the abovementioned Peruvian National Confidential Register – and their sharing with patent offices may be sufficient for achieving this objective.

The confidentiality of these databases would be particularly relevant when the indigenous or local community that holds the non-disclosed TK has no interest in making it publicly accessible, which is likely to be the vast majority of the cases. In such a situation, it is essential that the patent office assess the similarities between the information disclosed in the patent claims and the existing TK before the publication of the patent application and impede this publication if it concludes that the invention is based on the non-disclosed TK. Otherwise, the knowledge will become publicly available upon publication.

Second, the effects of the extension of the concept of prior art through its reinterpretation or by law will be restricted to countries that have adopted this understanding or measure. Due to the principle of territoriality and the absence of international standards that determine the exact scope of the prior art, it will not be possible to make defensive use of non-publicly available TK in countries which only consider the accessibility of information for the purposes of the determination of the prior art. As a consequence, most patent offices, including the largest

[106] See: Rai (n 101) 433–434; similarly, but pointing out the objective uncertainty regarding the notion of TK-related prior art in India Shravan Kalluri, 'Traditional Knowledge and Patent Strategy' (2012) 17 Journal of Intellectual Property Rights 430.

ones, such as the abovementioned EPO and USPTO or the German Patent and Trademark Office (DPMA),[107] will only consider publicly accessible TK for the assessment of novelty and inventive step during the patent examination. Countries interested in recognising the extended prior art for TK in other jurisdictions will have to seek it through international agreements, which will probably not be an easy task.

Third – and most important – it is questionable whether such a measure is compatible with the international patent law.

On the one hand, such compatibility could be supported by the fact that there is no formal definition of novelty in international patent treaties. As noted above, Art. 27.1 TRIPS leaves considerable flexibility for countries to determine the scope of this term. This has already been highlighted by the U.S. representatives in the TRIPS Council as follows:

> There is no definition of the term 'new' in the TRIPS Agreement or in the Paris Convention. In addition, Article 1.1 of the TRIPS Agreement states that 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. In view of these facts, there is no prescription as to how WTO Members define what inventions are to be considered 'new' within their domestic systems.[108]

Although there is general international consensus that novelty is related to the anticipation of yet unknown inventions,[109] the definition of prior art is subject to the different determinations and definitions of Member States.[110] Thus, nothing would prevent a country from determining that TK is not 'new' – since it already exists – even if it is not publicly accessible.

On the other hand, it has to be considered that the flexibility in determining novelty is usually used to *exclude* from its scope some information that is already publicly accessible (prior art) and by this means support the dissemination of knowledge. For example, under the former U.S. patent legislation, consideration was given to information only if it came from printed publication in foreign countries for prior art intended to disseminate within the USA information known or used

[107] From the German: Deutsches Patent- und Markenamt. This information results from an interview with the DPMA in March 2021.
[108] Council for Trade-Related Aspects and of Intellectual Property Rights, 'Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-Competitive Practices in Contractual Licences' World Trade Organization (1998) 5.
[109] Malbon, Lawson and Davison (n 10) 418. Recital 27.23.
[110] ibid 419. Recital 27.24.

abroad but not yet in its territory.[111] Likewise, temporal restrictions of the prior art in case of anticipation of the invention in an official international exhibition, as provided – for instance – by Art. 55(1)(b) EPC,[112] intend to promote the dissemination of the innovation in these events even if the inventor or other entitled person has not yet filed the respective patent application. In this sense, it is noteworthy that the promotion of technological innovation and the dissemination of technology are among the objectives of intellectual property protection according to Art. 7 TRIPS.[113]

However, by extending the scope of the prior art to non-publicly available TK and preventing an independently obtained invention from being patented, the law would not act towards these objectives. Conversely, under certain conditions, the uncertainty regarding the possibility of amortisation and recovery of investments through exclusive rights due to the possible coincidence between the innovation and an existing but non-disclosed TK could negatively affect the promotion of technological innovation in several sectors of biotechnology. As a consequence, the dissemination not only of non-publicly available TK, but also of further new technical knowledge could be significantly impaired.

In this regard, it should be highlighted that innovation by its very definition requires not only the emergence of new knowledge or a new product or process, but also its availability for potential users[114] as well

[111] Woodcock (n 9) 378; Anonymous, 'Novelty and Reduction to Practice: Patent Confusion' (1966) 75 Yale Law Journal 1198.

[112] EPC. Art. 55: '(1) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (…) (b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.'

[113] TRIPS. Art. 7 - Objectives: 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.' See also: Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell/Thomson Reuters 2012) 231. Recital 2.212; Eric M Solovy and Pavan Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines (June 12, 2017)' (2017) 50 George Washington International Law Review 90; Malbon, Lawson and Davison (n 10) 194. Recital 7.22.

[114] *Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation* (4th edn, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing 2018) 20. In its Guidelines, the OECD defines innovation as 'a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process).'

as a certain perception and acceptance by society.[115] Regardless of its relevance to the technical solution of a practical problem, non-disclosed TK is not an innovation in the strict sense whose protection could eventually equate with the detrimental treatment of information independently obtained by a third party.

Therefore, considering that the objectives of promotion of innovation and dissemination of technology set forth in Art. 7 are relevant to the interpretation of the scope of the other TRIPS provisions,[116] the extension of prior art to non-publicly available TK might be incompatible with the novelty requirement under Art. 27.1.

Although controversial,[117] it can in fact be affirmed that Arts. 7 and 8.1 TRIPS provide the member states with some flexibility to configure patent law at the national level in order to meet relevant public interests concerning socio-economic development, which may perhaps not be related to innovation and its dissemination.[118] However, even though impeding the undue appropriation of TK in respect of the cultural and historical context of indigenous and local communities may in fact be considered a relevant interest from a socio-economic perspective in certain Member States,[119] the restriction of patent rights in this case should be proportional and consider both the societal interests related to innovation and the interests of communities in a well-balanced manner.[120] Since the independent achievement of already existing but non-publicly available TK by a third party does not properly mean a 'misappropriation' of this knowledge and that society may have a relevant interest in the dissemination of this information, it is questionable whether this measure would be considered to be

[115] For a deeper analysis of this term, including reference to Schumpeter's concept of innovation, see: Gerard Marshall Raj and Neel Jayesh Shah, 'Intellectual Property Issues Surrounding Antimicrobial Agents', Intellectual Property Issues in Microbiology (Springer Singapore 2019) 3; Lukas Mester, 'Was ist eigentlich Innovation?' iteractec.

[116] Matthew Turk, 'Bargaining and Intellectual Property Treaties: The Case for A Pro-Development Interpretation of Trips but Not Trips Plus' (2010) 42 New York University Journal of International Law and Politics 981, 1007; Gervais (n 110) 230. Recital 2.111; Solovy and Krishnamurthy (n 110) 90.

[117] For a contrary opinion, see: Malbon, Lawson and Davison (n 10) 236. Recital 8.70; Gervais (n 110) 238. Recital 2.123; Solovy and Krishnamurthy (n 110) 91. Joseph Straus, 'Patentschutz durch TRIPS-Abkommen - Ausnahmeregelungen und -praktiken und ihre Bedeutungen, insbesondere hinsichtlich pharmazeutischer Produkte,' Bitburger Gespräche (2003).

[118] Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007) 95; Peter Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 Houston Law Review 1000; Hilty and Lamping (n 5) 13. Recital 1.2, 1.3.

[119] On the competence of the TRIPS Member States to define what constitutes a relevant public interest within their own jurisdictions, see: Correa (n 115) 97.

[120]Max Wallot, 'The Proportionality Principle in the TRIPS Agreement' in Hanns Ullrich and others (eds), TRIPS plus 20 (Springer Berlin Heidelberg 2016) 221; Yu (n 115) 1004; Alison Slade, 'Articles 7 and 8 of the TRIPS Agreement: A Force for Convergence within the International IP System' (2011) 14 The Journal of World Intellectual Property n/a, 420.

proportional. In any case, there is still no case-law of the Dispute Settlement Body of the World Trade Organization that brings concrete indications as to the compatibility of the extension of the prior art to non-disclosed TK with the TRIPS Agreement.

VI. CONCLUSION AND RECOMMENDATIONS

The patenting of TK-based inventions is often against the interests of the indigenous and local communities in which they originate, who may not wish to see a third party exercising exclusive rights over their knowledge as a matter of principle or given the potential risks of sharing benefits derived from its use. The defensive use of TK can at least prevent the patenting of inventions that do not meet the requirements of novelty and inventive step. Since TK must belong to the prior art for this purpose, the effectiveness of this defensive use depends on several factors and can be leveraged by others.

First, the written publication of TK, especially in print, enhances the effectiveness of its defensive use. From a legal perspective, and following the example of the former US legislation and the current PCT regulations on the international phase of the patent examination, such publication may eventually be a requirement without which the TK cannot be considered as in the prior art. From a practical point of view, it facilitates patent examiners' identification of the information, given that their patent searches are usually restricted to written and published sources. Further, a more technical description of the TK is recommended, particularly concerning the concrete use and application of certain biological or genetic resources to solve specific problems. The description may address the properties of the resources used, dosages, form of application, or contraindications. Moreover, here the language accessibility is equally important to increase the likelihood that TK will be recognised as prior art.

Second, databases that compile, structure and organise TK can be an essential tool to play a defensive protection role. For the sake of effectiveness, these databases should, like publications, consist of technical descriptions of the TK in a language accessible to foreign examiners. Open databases that feature those characteristics are sufficient to place TK in the prior art. Targeted dissemination among patent offices and the presence on the WIPO TK databases list can guarantee that the patent examiners fully consider them. Further attention is necessary in the case of restricted databases, since they are not publicly accessible. In such cases, it is necessary to make the restricted databases available to the patent offices of interest and provide express references to elements that prove that each piece of TK contained therein is encompassed by the prior art, e.g., publications. Otherwise, this knowledge may not be considered prior art.

Third, the legal extension of the prior art to TK that is not publicly accessible could enhance the effects of the defensive function by preventing the patenting of inventions based on this knowledge even though it is only available to the community that holds it. In this case, third parties who independently obtain this existent but non-disclosed knowledge would not be able to obtain patents directly related to them. Although such a measure may take into account the viewpoint of certain indigenous and local communities on the concept of prior art from a cultural perspective and more extensively curb the appropriation of TK, its scope of application would be restricted to countries that adopt it. Further, it is questionable whether this extension of the concept of prior art is compatible with international patent law.

Countries and communities interested in guaranteeing the communities' right to grant access to their TK only after a previous informed consent and through mutually agreed terms should consider that the publication of this knowledge and the creation of open databases can make the control of third parties' access difficult. The creation of a restricted database like the Indian TKDL is a good alternative to promote the defensive use of TK without harming this interest.

It is worth noting that this defensive use does not prevent all inventions based on TK from being patented. Despite the use of TK in the prior art, inventions associated with complementary knowledge that duly meet the requirements of novelty, inventive step, and industrial application may be patented.[121] The concrete conditions for this may vary from country to country according to their substantive patentability requirements.

Finally, the decision to create a TK database *only* for the purpose of effective defensive use of the TK requires an economic consideration by the interested parties. Having an established TK database to serve as a source for prior art searches, they can avoid the high costs of administrative and court battles related to the revocation and invalidity of an improperly granted patent.[122] However, the establishment of TK databases itself requires a high investment. Even considering the well-known Indian TKDL, it is still unclear whether the investment has been compensated by the few dozen cases where patent offices have considered its contents during the examination[123] and by the even fewer cases in which the TK contained therein was considered *ex officio* by patent examiners. Careful analysis must take place before any decision to implement a TK database is made.

[121] Reid (n 2) 416.
[122] ibid 93.
[123] Prashant Reddy Thikkavarapu and Sumathi Chandrashekaran, 'Why the Traditional Knowledge Digital Library's Existence Deserves a Thorough Relook' *The Wire* (2017) <https://thewire.in/science/tkdl-csir-neem-patents> accessed 23 April 2021.

Bibliography

Alejandro Argumedo and others, 'The Role of Registers and Databases in the Protection of Traditional Knowledge: A Comparative Analysis' United Nations University Institute of Advanced Studies (2004).

Alison Slade, 'Articles 7 and 8 of the TRIPS Agreement: A Force for Convergence within the International IP System' (2011) 14 The Journal of World Intellectual Property.

Anand Chaudhary and Neetu Singh, 'Intellectual Property Rights and Patents in Perspective of Ayurveda' (2012) 33 AYU (International Quarterly Journal of Research in Ayurveda).

Anonymous, 'Novelty and Reduction to Practice: Patent Confusion' (1966) 75 Yale Law Journal 1198.

Brice C Lynch, 'International Patent Harmonization: Creating a Binding Prior Art Search within the Patent Cooperation Treaty Note' (2012) 44 George Washington International Law Review.

Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007).

Chidi Oguamanam, 'Wandering Footloose: Traditional Knowledge and the 'Public Domain' Revisited' (2018) 21 Journal of World Intellectual Property.

Christina Federle, Biopiraterie und Patentrecht (Nomos 2005).

Council for Trade-Related Aspects and of Intellectual Property Rights, 'Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-Competitive Practices in Contractual Licences' World Trade Organization (1998).

Council of Yukon First Nations, 'Cultural Orientation and Protocols Toolkit Council of Yukon First Nations' (2010) <http://lss.yukonschools.ca/uploads/4/5/5/0/45508033/part_7_lfn.pdf> accessed 14 May, 2021.

CSIR, 'Traditional Knowledge Digital Library – Insomnia' Council of Scientific & Industrial Research | CSIR | GoI (June 25, 2020) <https://www.csir.res.in/documents/tkdl> accessed 23 April 2021.

Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell/Thomson Reuters 2012).

Darrell Addison Posey, 'Indigenous Peoples and Traditional Resource Rights: A Basis for Equitable Relationships?' (1995).

Donald Chisum, 'Sources of Prior Art in Patent Law' (1976) 52 Washington Law Review.

Dylan O Adams, 'Patents Demystified: An Insider's Guide to Protecting Ideas and Inventions' (American Bar Association 2015)

Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* (Brill 2014).

Eric M Solovy and Pavan Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines (June 12, 2017)' (2017) 50 George Washington International Law Review.

Francis Kariuki, 'Protecting Traditional Knowledge in Kenya: Traditional Justice Systems as Appropriate Sui Generis Systems', *WIPO-WTO Colloquium Papers* (2019).

Gerard Marshall Raj and Neel Jayesh Shah, 'Intellectual Property Issues Surrounding Antimicrobial Agents', Intellectual Property Issues in Microbiology (Springer Singapore 2019).

Hetal Patel and Sandesh Lodha, 'Case Study on Rejected Patents in India' Intellectual Property Rights - Patent (IntechOpen 2020) <https://www.intechopen.com/books/intellectual-property-rights-patent/case-study-on-rejected-patents-in-india> accessed 8 June 2021.

Horst-Peter Götting, 'Biodiversität und Patentrecht' (2004) GRUR Int.

Jane Anderson, 'Indigenous/Traditional Knowledge and Intellectual Property' (2010) Duke University School of Law – Center for the Study of the Public Domain.

Jin-Seop Shin, Yu-Seon Lee and Myung-Sun Lee, 'Protection and Utilization of Traditional Knowledge Resources through Korean Traditional Knowledge Portal (KTKP)' (2010) 10 The Journal of the Korea Contents Association.

Joelle Dountio, 'The Protection of Traditional Knowledge: Challenges and Possibilities Arising from the Protection of Biodiversity in South Africa' (2011) 26 SAJAH.

John Reid, 'Biopiracy: The Struggle for Traditional Knowledge Rights' (2009) 34 American Indian Law Review.

John T Cross, 'Property Rights and Traditional Knowledge' (2010) 13 Potchefstroom Electronic Law Journal (PELJ).

Joseph Straus, 'Patentschutz durch TRIPS-Abkommen - Ausnahmeregelungen und -praktiken und ihre Bedeutungen, insbesondere hinsichtlich pharmazeutischer Produkte,' Bitburger Gespräche (2003).

Justin Malbon, Charles Lawson and Mark Davison, The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary (Edward Elgar 2014).

Kelly Bannister and Preston Hardison, 'Mobilizing Traditional Knowledge and Expertise for Decision-Making on Biodiversity' (2006).

Kelly Sanchez, 'The Problem with the Biopiracy in Peru' (2019) China IP Magazine <http://www.chinaipmagazine.com/en/news-show.asp?id=10654> accessed 8 June 2021.

Klaus-Jürgen Mellulis, 'Art. 54 – Neuheit' in Georg Benkard and others (eds), *Europäisches Patentübereinkommen*, vol 4 (CH Beck 2018).

Lakshmi Poorna, Mymoon Moghul and Hariharan Arunachalam, 'Preservation and Protection of Traditional Knowledge – Diverse Documentation Initiatives across the Globe' (2014) 107 Current Science.

Lukas Mester, 'Was ist eigentlich Innovation?' iteractec < https://explore.iteratec.com/blog/was-ist-eigentlich-innovation> accessed 02 July 2021.

Maria Luiza Grabner, 'Conhecimentos Tradicionais: Proteção Jurídica e Diálogo Intercultural' (USP 2009).

Matthew Turk, 'Bargaining and Intellectual Property Treaties: The Case for A Pro-Development Interpretation of Trips but Not Trips Plus' (2010) 42 New York University Journal of International Law and Politics.

Max Wallot, 'The Proportionality Principle in the TRIPS Agreement' in Hanns Ullrich and others (eds), TRIPS plus 20 (Springer Berlin Heidelberg 2016).

Michael C Ogwezzy, 'Protection of Indigenous or Traditional Knowledge Under Intellectual Property Laws: An Examination of the Efficacy of Copyright Law, Trade Secret and Sui Generis Rights' (2012) 12 International and Comparative Law Review.

Mora Rodríguez, 'Engineering the Patent System in the Global ICT Market: A Critical Analysis' (2011).

National Biodiversity Authority, 'People's Biodiversity Register' (2013) <www.nbaindia.org> accessed 8 June 2021.

Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation (4th edn, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing 2018).

Paul Ongugo and others, 'Protecting Traditional Health Knowledge in Kenya: The Role of Customary Laws and Practices' (2012).

Paul Schwander, 'Traditional Knowledge and TKDL at the EPO' (2011). <https://www.wipo.int/edocs/mdocs/tk/en/wipo_tkdl_del_11/wipo_tkdl_del_11_ref_t7_1.pdf> accessed 23 April 2021.

Peter Mes, *Patentgesetz, Gebrauchsmustergesetz: Kommentar* (CH Beck 2020).

Peter Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 Houston Law Review.

Philip M Webber, 'Priority Patent Applications' (2005) 4 Nature Reviews Drug Discovery.

Prashant Reddy Thikkavarapu and Sumathi Chandrashekaran, 'Why the Traditional Knowledge Digital Library's Existence Deserves a Thorough Relook' *The Wire* (2017) <https://thewire.in/science/tkdl-csir-neem-patents> accessed 23 April 2021.

Rebecca Goldman Rudich, 'Novelty and Grace under the AIA' in John M White (ed), *Patent Eligibility, Prior Art and Obviousness 2017: Current Trends in Sections 101, 102 and 103* (Practising Law Institute 2017).

Reto M Hilty and Matthias Lamping, 'Declaration on Patent Protection – Regulatory Sovereignty under TRIPS' (2016).

Reto M Hilty. 'Rationales for the Legal Protection of Intangible Goods and Cultural Heritage' (2009) International Review of Intellectual Property and Competition Law (IIC).

Robert P Merges, 'Priority and Novelty Under the AIA' (2012) 27 Berkeley Technology Law Journal.

Rudolf Kraßer and Christoph Ann, *Patentrecht: Lehrbuch zum deutschen und europäischen Patentrecht und Gebrauchsmusterrecht* (CH Beck 2016), 281.

Ruth Okediji, 'Traditional Knowledge and the Public Domain - Centre for International Governance Innovation' (2018) CIGI Paper No. 176.

Sangeeta Udgaonkar, 'The Recording of Traditional Knowledge: Will It Prevent "Bio-Piracy"?' (2002) 82 Current Science.

Secretariat of the Convention on Biological Diversity, 'Composite Report on the Status and Trends Concerning the Knowledge, Innovations and Practices of Indigenous and Local Communities (UNEP/CBD/WG8J/4/INF/9)' (2006).

Shravan Kalluri, 'Traditional Knowledge and Patent Strategy' (2012) 17 Journal of Intellectual Property Rights.

Shubha Ghosh, 'Globalization, Patents, and Traditional Knowledge' (2003) 17 Columbia Journal of Asian Law.

Srividhya Ragavan, 'Protection of Traditional Knowledge' (2005) 2 SSRN Electronic Journal.

Suchi Rai, 'Traditional Knowledge And Scope For Patent Protection - Intellectual Property - India' [2018] mondaq <https://www.mondaq.com/india/patent/668414/traditional-knowledge-and-scope-for-patent-protection?login=true> accessed 8 June 2021.

Susette Biber-Klemm and Thomas Cottier, Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives (CABI Pub 2006).

Sylvia Bazán Leigh, 'A Cuatro Años de La Ley N.° 27811: Algunas Interrogantes En Torno a Su Aplicación' (2008) 4 Anuario Andino de Derechos Intelectuales.

Tejaswini Apte, 'A Simple Guide to Intellectual Property Rights, Biodiversity and Traditional Knowledge | Publications Library' (2006).

UNCTAD, 'Dispute Settlement' (2003) <www.unctad.org> accessed June 7, 2021.

UNESCO World Heritage Centre, 'WHC-08/32.COM/24Rev: 32nd Session of the World Heritage Committee' (2008).

Virgil E. Woodcock, 'What Is Prior Art' (1958) 3 Vll. L. Rev.

Viviane Alves Bertogna, 'Biodiversidade e Propriedade Intelectual No Brasil' (FADUSP 2003).

VK Gupta, 'TK Documentation and Defensive Protection: An Example from India' Intellectual Property and Sustainable Development: Documentation and Registration of TK and Traditional Cultural Expressions (2011) <https://www.wipo.int/edocs/mdocs/tk/en/wipo_tk_mct_11/wipo_tk_mct_11_ref_t_5_1.pdf> accessed 8 June 2021.

Wend B Wendland, 'Intellectual Property, Traditional Knowledge and Folklore: WIPO's Exploratory Program', (2002) IIC.

World Intellectual Property Organization, 'Certain Aspects of National/Regional Patent Laws – Grace Period' (2020).

World Intellectual Property Organization, 'Draft Quick-Win Online Databases and Registries of Traditional Knowledge and Genetic Resources' (2016).

World Intellectual Property Organization, 'Introduction to Intellectual Property: Theory and Practice' (Kluwer Law International BV 2008).

World Intellectual Property Organization, 'Meeting of International Authorities under the Patent Cooperation Treaty: Document Submitted by India (PCT) (PCT/MIA/22/8)' (2015).

World Intellectual Property Organization, 'Report on the Status of Traditional Knowledge as Prior Art (WIPO/GRTKF/IC/2/6)' (2001).

World Intellectual Property Organization, 'Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources (WIPO/GRTKF/IC/4/14)' (2002).

World Intellectual Property Organization, 'The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit' (2012).

World Intellectual Property Organization, 'Documenting Traditional Knowledge – A Toolkit' (2017).

Zhongdi Liu and others, 'Application of Traditional Chinese Medicine in Medical Practice: A Survey of Community Residents in Beijing, China' (2017) 37 Journal of traditional Chinese medicine = Chung i tsa chih ying wen pan.