Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property

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ABSTRACT

Traditional knowledge (TK) is the information that people in a given community, based on experience and adapted to local culture and environment, have developed over time and that continues to develop. This knowledge is used to sustain the community and its culture, as well as the biological resources necessary for the continued survival of the community. Since 1948, international human-rights standards have recognized the importance of protecting intellectual property. Yet, to date, intellectual property (IP) rights are not adequately extended to the holders of TK. The requirements for IP rights protections under current IP regimes remain largely inconsistent with the nature of TK. As a result, it is neglected and considered part of the public domain with no protections or benefits for the knowledge holders, or expropriated for the financial gains of others, often referred to as biopiracy. This chapter presents basic IP concepts in the context of TK with specific attention to identifying, classifying, and protecting elements of TK. The advantages and disadvantages of the various IP protection options are discussed, and a number of case studies are presented to facilitate a better understanding of each option or issue.

1. INTRODUCTION

Traditional knowledge (TK) is information that people in a given community, based on experience and adaptation to a local culture and environment, have developed over time and continue to develop. The knowledge is used to sustain the community and its culture and to maintain the genetic resources necessary for the community's continued survival. Key examples of TK are these uses of biological resources:

- *plao-noi* in Thailand for the treatment of ulcers
- the *hoodia* cactus by Kung Bushmen in Africa to stave off hunger
- turmeric in India for wound-healing
- *ayahuasca* in the Amazon basin for sacred religious and healing purposes
- *j'oublie* in Cameroon and Gabon as a sweetener

TK includes mental inventories of local biological resources, animal breeds, and local plant, crop, and tree species. It may include such information as which trees and plants grow well together and which are "indicator plants" (plants that show soil salinity or are known to flower at the beginning of the rains, for example). TK includes practices and technologies, such as seed treatment and storage methods and tools used for planting and harvesting. It also encompasses belief systems that play a fundamental role in peoples' livelihoods, maintain their health, and protect and replenish the environment. TK is dynamic in nature and may include experimentation in the integration of new plant or tree species into existing farming systems or a traditional healer's tests of new plant medicines.

Hansen SA and JW Van Fleet. 2007. Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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The term *traditional* used in describing this knowledge does not imply that it is old or untechnical in nature, but that it is tradition based. It is traditional because it is created in a manner that reflects the traditions of the originating communities, therefore not relating to the nature of the knowledge itself, but to the *way* in which that knowledge is created, preserved, and disseminated.[1]

TK is collective in nature and is often considered the property of the entire community, not belonging to any single individual within the community. TK is transmitted through specific cultural and traditional information-exchange mechanisms—for example, orally through elders or specialists (breeders, healers, and so on)—and often to only a select few people within a community.

The knowledge and uses of specific plants for medicinal purposes (often referred to as traditional medicine) is an important component of TK. Once, traditional medicines were a major source of materials and information for the development of new drugs. In the 20th century, however, new sources for pharmaceuticals led to a decline in the importance of ethnobotany in drug-discovery programs. However, new discoveries of potentially potent anticancer agents in plants (such as turmeric and taxol), as well as a rapidly growing herbal remedies market, have revived industry interest in traditional medicinal knowledge and practices. As interest in traditional medicine is rekindled, indigenous knowledge of the cultivation and application of genetic resources is being exploited at an alarming rate.

IP (intellectual property) rights should guarantee both an individual's and a group's right to protect and benefit from its own cultural discoveries, creations, and products. But Western IP regimes have focused on protecting and promoting the economic exploitation of inventions with the rationale that doing so promotes innovation and research. Western IP law, which is rapidly assuming global acceptance, often unintentionally facilitates and reinforces a process of economic exploitation and cultural erosion. It is based on notions of individual property ownership, a concept that is often alien to indigenous communities and can be detrimental to them. An important purpose of recognizing private proprietary rights is to enable individuals to benefit from the products of their intellect by rewarding creativity and encouraging further innovation and invention. But in many indigenous worldviews, any such property rights, if they are recognized at all, should be extended to the entire community. They are a means of maintaining and developing group identity, as well as group survival, rather than promoting or encouraging individual economic gain.

2. IP PROTECTION OPTIONS FOR TK HOLDERS[2]

2.1 *Patents*

Patents provide a legal monopoly over the use, production, and sale of an invention, discovery, or innovation for a specific period of time (usually about 20 years). A monopoly is the right to exclusive control over the use, development, and financial benefits derived from a patented item. In order for an invention or innovation to be patentable, it generally must meet three criteria: novelty, nonobviousness, and industrial application (or utility). Indeed, it must meet all of these criteria, and if one can be disproved, the patent cannot be approved.

Novelty refers to the "newness" of an invention, in other words, there is no prior art. Prior art is the knowledge base that existed before the invention was discovered or before the invention was disclosed by filing a patent application.

Nonobviousness refers to the presence of an inventive step, that is, the invention or innovation must not have been obvious at the time of its creation to anyone having "*ordinary skill in the art.*"[3]

Industrial application, or utility, refers to the very reason for patent protection, that is, to promote the progress of the useful arts. For a product or process to be useful it must, at least, work, although it does not have to work perfectly or even better than any competing products or processes, nor does there have to be a market for the invention (nor even a potential market).

For several reasons, patents might not represent the most advantageous form of IP rights protection for TK. First, applying for a patent requires full disclosure of (making public) the invention or innovation. Shortly after the patent is approved, the information is placed in the public domain by making the patent application publication available to the public. In the United States, a patent is made public 18 months after it is approved. If the TK is considered a *trade secret*, a patent may not be the most appropriate IP solution. Second, the invention or innovation must be novel according to patent-office standards. The patent applicant must prove that the invention or innovation is not part of the current prior-art base as defined by each country's legal definition of *novelty*. In many countries, TK may be considered, de facto, part of the prior-art base. This task can either be simple or somewhat difficult, but nonetheless, it must be demonstrated.

2.2 *Petty-patent models*

Petty patents allow for protections similar to those of patents, but for knowledge consisting of a less-detailed inventive step.[4] The knowledge must still meet the novelty and industrial-application criteria. The term of protection for a petty patent is typically between four and six years, which is shorter than the term for the standard patent.

The petty patent exists only in a few countries and is not mentioned in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a minimum standard for IP protection. However, some countries are pushing for the inclusion of petty patents in the TRIPS Agreement. Petty patents may be more suitable for TK, as TK is not typically documented in the same manner as Western science. Despite the fact that petty patents are not globally recognized as a minimal standard for IP protection, some countries have enforced the mechanism as a way of protecting TK. For example, a type of petty patent is mentioned in Kenyan legislation in order to protect indigenous claims to traditional herbal medicine.[5] Although the current application of petty patents is relatively small, their implementation at a broader level could serve TK as a viable IP protection option.

2.3 *Plant variety protection/ plant breeders' rights*

Many countries protect plant varieties with the plant variety protection certificate. This mechanism is used to protect the rights of breeders of sexually reproducing (by seed) varieties of plants. Breeders' rights protect the commercial interests of the breeder so that economic incentives exist for continued breeding of new plant varieties, ultimately serving farmers or those who grow the varieties. Importantly, unlike utility patents, plant variety certificates do not require the authorization of the breeder for use of the variety by others for further breeding purposes.

The criteria for a plant variety protection certificate are fairly uniform across countries that offer them. The variety must meet all of these criteria:

- distinct from existing, commonly known varieties
- sufficiently uniform
- stable
- novel[6]

The International Convention for the Protection of New Plant Varieties (UPOV) is not a legal mechanism per se. Rather, UPOV is an international treaty and an organization that sets certain standards. A country can only become a member of UPOV if its plant variety protection schemes meet these minimum standards. Importantly, under the TRIPS agreement, countries are bound to enact sui generis protection for plants, and the UPOV requirements are generally considered to meet such standards.

Proposals for legislation in Nicaragua have included provisions that require ten unique characteristics in order to distinguish a variety as *distinct*; to exclude protection for "discovered" plants; and, not to extend plant breeders' rights to plants used for food or sown directly by farmers. Zambia has cited the Convention on Biological Diversity (CBD)[7] in developing its plant variety protection mechanism and states that any final legislation must recognize and reward indigenous

innovation. India's Plant Variety Protection Act (2001) declares that the rights of the farmer supercede those of the breeder. The Plant Varieties Protection Act of Bangladesh (1998) states that a variety must have *"immediate, direct and substantial benefit to the people of Bangladesh,"*[8] and protects both community and farmers' rights.[9] These examples demonstrate that options other than UPOV can be established that effectively address the needs of TK holders.

2.4 *TK registries*

Public registries place information in the public domain and serve as a form of prior art or *defensive disclosure*. They can be public or private. A defensive disclosure, by describing information in a printed publication or other publicly accessible medium, helps to establish prior art capable of preventing patents.

2.4.1 *Public registries*

TK registries are official collections of documentation that describe TK (see Box 1). Registries can be established and maintained either locally (within a community) or outside a community (external), even for an entire country (see Box 2). With a locally maintained registry, the community may collectively decide what is to be included in the registry and what knowledge is to be shared and/or disclosed to people outside the community.

2.4.2 *Private registries*

Private registries do not place knowledge in the public domain. But private registries can be effective as:

- protection mechanisms for TK in instances where a sui generis system is in place
- preservation mechanisms when cultural and historic preservation is a goal
- tools for access and benefit-sharing agreements

Since the information in a private registry is documented but is not in the public domain, it may not constitute prior art capable of preventing a patent based on the knowledge by an outsider. The knowledge in a private registry cannot prevent the approval of a patent under most IP systems unless the knowledge constitutes prior art through a sui generis mechanism and disclosed to patent authorities. However, it may be possible to challenge and revoke a patent with knowledge documented in a private registry if patent law recognizes prior art not disclosed to the public as being admissible under a sui generis system. Reexamination requests of patents can be both costly and time consuming. Also, the knowledge may need to be disclosed to the public if no sui generis protection mechanism exists that would prohibit its public disclosure during reexamination.

Because the recognition and effectiveness of private registries varies from country to county, private registries are most effective as a mechanism for preservation of knowledge and as a tool for access and benefit-sharing agreements. A private registry can serve as a catalog for knowledge that can be licensed to outside parties for research and product development. As a mechanism for cultural preservation, the private registry serves as a cultural library that documents and maintains TK belonging to a community and helps prevent loss of the TK (see also Box 2).

A typical form of registry is a computer database. The Internet is an ideal location for public databases containing TK, as they can serve as a vehicle for defensive disclosure and are accessible to patent offices worldwide as a source of prior art. The World Intellectual Property Organization (WIPO) is in the process of compiling a list of TK-related databases for international patent offices, and several large public databases collect TK as a means of defensive disclosure against the misappropriation of IP.

The benefit of both public and private registries lies in their ability to prevent or revoke inappropriate claims of IP rights. In order to be effective in this manner, it is essential that national patent offices are made aware of the public registry for use in prior-art searches. The public registry has the additional benefits of negating the application of IP rights on TK prior to patent approval and promoting free use of the knowledge in the public domain for everyone's benefit.

Box 1: An Example of TK Documentation

To illustrate how a claim may be documented, an entry from the Honeybee Network's Innovation Database is provided here. That database is a large online database of grassroots innovations detailing contemporary and traditional innovative practices.

Claim[a]	To illustrate how a claim may be documented, an entry from the Honeybee Network's Innovation Database is provided here. That database is a large online database of grassroots innovations detailing contemporary and traditional innovative practices.
Inventor[a]	Hirabhai Kodarbhai Raval
Address of innovator	Sabarkantha Gujarat
Details of innovation	Hirabhai Kodarbhai Raval has a special way of treating his animals for stiffness of the body. He prepares a mixture of 250 g variyali (*Foeniculum vulgare*), 50 g turmeric powder, and 500 g Dalda ghee. This, when given to the animal to drink, loosens the stiffness in the body of the animal and relieves joint pains. Half this dosage is prescribed for very young animals.
Reference from	Honey Bee, 9(4): 15, 1998

Note that this database entry contains the following information:

Claim being made: Curing joint pains (In this format for documentation, the claim also serves as the name or descriptive title for the claim.)

Name of the inventor or claimant: In this example, the inventor is an individual, but this could be the name and/or location of a community as well.

Details of the invention: It is a mixture consisting of the following ingredients and amounts: 250 grams of variyali (*Foeniculum vulgare*), 50 grams of turmeric powder, and 500 grams of Dalda ghee.

How applied: It is given to the animal to drink.

Dosage: As mixed and half dosage for very young animals

Results: Loosens the stiffness in the body of the animal and relieves joint pains

a Term added by the authors.

2.5 *Trade secrets*

Trade secrets protect undisclosed knowledge through access agreements, which may involve paying royalties to knowledge holders for access to and the use of their knowledge. Three elements are required for knowledge to be classified as a trade secret. The knowledge:

- must have commercial value
- must not be in the public domain
- is subject to reasonable efforts to maintain secrecy

TK that is maintained within a community could be considered a trade secret. But once the knowledge is made public, this option no longer exists. A trade secret is only enforceable as long as it remains a secret. Trade secrets have no legal protection except in cases of "*breach of confidence and other acts contrary to honest commercial practices.*"[12] This means that one must be able to prove some form of malicious intent on the part of a contracting party as the cause for a trade secret's diffusion to the public in order to be compensated for the loss of secrecy.

It is important to remember that knowledge considered a trade secret can be used by anyone if the knowledge is leaked into the public domain, is independently discovered by another individual, or is reverse engineered. It is difficult to protect trade secrets against misappropriation due to lack of legal entitlement to the bearer of the secret. When applied to knowledge belonging to a community, the community must make a reasonable effort to maintain the secrecy. If there is not a reasonable effort to maintain secrecy with respect to the TK, then trade secret protection is not applicable to it.

2.6 *Trademarks*

The U.S. Patent and Trademark Office (PTO) defines *trademark* as "*a word, phrase, symbol or design, or a combination of words, phrases, symbols or designs, that identifies and distinguishes the source of the goods of one party from those of others.*"[13] In other words, trademarks are a way of protecting the use of words, phrases, symbols, designs, or any combination of these associated with a product. Once a trademark is established, it can be used to

Box 2: A Public Registry in India

One example of a public registry is the people's biodiversity registers (PBRs) in India. Recognized in the Indian Biological Diversity Bill of 2000, the PBRs consist of records of people's knowledge of biodiversity, its use, trade, and efforts for its conservation and sustainable utilization. The PBRs are developed at the village level by a local school and college teachers, students, and nongovernmental (NGO) researchers, and villagers. Biodiversity registers are then compiled in the form of computerized databases at the levels of talukas, districts, states, and the entire country, in order to provide information to the public, government, and industry. These PBRs have been recognized by the Indian Biological Diversity Bill as a form of prior art in the evaluation of patent applications, as well as serving to ensure equitable access and benefit sharing.

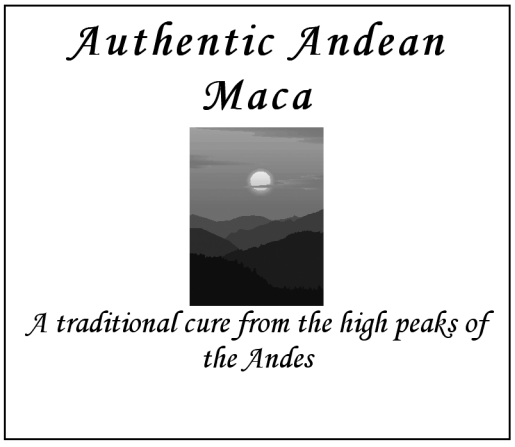
External registries are maintained outside the community, often on the national or international level, by governments, NGOs, museums, or libraries. These registries can be collections of TK specific to one particular community or to several communities. Local communities may have control over what is entered into the registry, but may not be responsible for the registry's maintenance. Distinguishing between local or external registries is at the discretion of the TK stakeholders.

A disadvantage of the public registry is the disclosure of knowledge to others outside the community. When placing knowledge in the public domain, the knowledge may lose its commercial value, limit options for IP protection for the community, and may be used by the public without permission.

identify and differentiate similar products. Think how often names, images, and photos are always used in marketing products.

Trademarks are based on two principles: distinctiveness and avoiding confusion. Being distinct means that the trademark does not resemble any other existing word, phrase, symbol, design, and so on, associated with a similar product. Avoiding confusion as to the source of a product is important for consumers purchasing these products. Trademarks distinguish products in order not to mislead consumers into thinking that a product is something that it is not or that it comes from another source.

How can trademarks be applied to TK? Suppose a company sells a product composed of *maca*, a plant native to the Andean region. An indigenous community in the Andes, the original knowledge holders of *maca*'s uses, may also want to sell *maca* or profit from their own natural resources and knowledge. They could register a trademark like the example below:



The indigenous group can register the above trademark and sell *maca* using this symbol to distinguish the brand.

2.7 *Geographical indicators*

A geographical indicator identifies a good as originating in a territory or region, or locality in that territory, where a given quality, reputation, or other characteristic of the good is attributable to its geographical origin.[14] Like trademarks, geographical indicators are typically words or terms, but when associated with a product, positively attribute a known quality to the product that is associated with a specific geographical location.

A geographical indicator cannot be used to describe a product unless it originates in the region associated with the name. For example, Swiss watches are associated with a tradition of high quality, so the term *Swiss watch* is a geographical indicator that assumes a watch came from Switzerland. Roquefort cheese (from France) is another product associated with high quality and constitutes a geographical indicator. Roquefort cheese can only be used to describe cheese produced in Roquefort-sur-Soulzon, France, and aged in the traditional caves (a practice also associated with the geographical indicator).

Other examples of geographical indicators include Bordeaux wine (France), Parma ham (Italy), Stilton cheese (United Kingdom), Darjeeling tea (India), Cognac (France), and Queso Murcia (Spain).

Geographical indicators serve four main purposes. They:

- identify where the product is from (its source)
- indicate the unique qualities of a product
- promote the product with a distinguishing name (for business purposes)
- prevent infringement and unfair competition by establishing a legal basis for using a location name to avoid confusion with similar products [15]

A specific form of geographical indicator is called an *appellation of origin*. Appellations of origin specify the quality of a product based on its geographical environment and are protected under the Lisbon Agreement of 1958. Twenty countries are party to the Lisbon Agreement. In 1998, of the 766 protected appellations of origin, 95% belonged to European countries.[16] Countries such as India and Bulgaria have recently been highly active in seeking *appellation of origin* protection for many of their products.

Preemptive protection of geographical indicators will ensure that they are commonly known and documented. This can be done by placing the geographical indicator in the public domain via a database or other publicly accessible medium.

The second option is to apply for a certification mark that is an official registration (as opposed to an unofficial disclosure of the indicator in the public domain). The certification mark is a type of trademark. Currently, international registry protection is available only for wines, and all other products are subject to national registry laws.[17]

If a country is party to the TRIPS Agreement, it is the country's international legal obligation to formulate legislation protecting geographical indicators. Article 22 of the TRIPS agreement states that members must provide legal means to prevent:

the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good.[18]

Additionally, the TRIPS Agreement requires the protection of what is defined as unfair competition in the Paris Convention.[19] "*All acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor*" shall be prohibited under this article.[20]

What does all this mean in the everyday life of a TK holder? Let's examine an example that adequately explains the importance of a geographical indicator. The *maca* plant is native to the high peaks of the Andes Mountains where it thrives in the high altitudes. Suppose a Western company was to modify the plant so that it could grow in lower elevations. Then, that company was to grow large quantities of the plant in the United States and market the plant product as "Andean *maca*." This is a clear violation of the provisions that protect against the improper use of geographical indicator. Andean *maca* is associated with a distinguished quality, and by using the name, the product, which is not produced in the Andes, misleads consumers into believing both that:

- the product was actually cultivated in the Andes
- the product is of the quality as that produced in the Andes

Only *maca* grown in the Andes, then, is permitted to be marketed as "Andean *Maca*" if:

- Andean-grown *maca* is commonly known to be of superior quality to other *maca,* and this fact is documented in the public domain
- a certification mark has been officially registered with a federal government for "Andean *maca*"

3. PRIOR ART AND DEFENSIVE DISCLOSURE

When determining whether a claim is novel, either through the filing of a patent application or during the patent application review process, the prior-art base (the public domain) is examined. If the invention or claim is found described in the prior-art base or has been offered for use or sale for more than one year, it is not entitled to a patent. In U.S. patent law, *prior art* is defined as a publication printed either in the U.S. or a foreign country describing the invention or discovery and dated more than one year before a patent's filing date or, simply, dated before the act of invention or conception. A publication may include any document accessible to persons working in a certain profession or field and therefore skilled in the relevant art. These could include magazines, trade or scientific journals, newsletters, newspapers, and Web sites, to name but a few.

The European patent system does not limit evidence of prior art solely to printed publications, but includes everything made available to the public by the means of a written or oral description, by use or by any other way, anytime before the patent application filing date.[21] The difference between the U.S. and European definition of *prior art* has serious implications for the recognition of TK as prior art, as much TK is not documented nor published, but is shared orally, or publicly known through demonstrated and public use.

Prior art is taken into account for the nonobvious requirement in applying for a patent. In many cases, the prior art may prove to be very similar, but not exactly like the claim or invention itself, but the differences would be obvious

to someone with ordinary skill in the area and who knew, or had relatively easy access to, the prior-art base.

3.1 *Defensive disclosure*

Defensive disclosure refers to information or documentation intentionally made available to the public as prior art in order to render any subsequent claims of invention or discovery ineligible for a patent. A defensive disclosure provides evidence of the invention, knowledge, or use of the invention by others before it was claimed by another inventor or offers evidence of public use or sale more than one year before the filing date of the patent.[22]

Defensive disclosures can be made anonymously without attributing the knowledge to a particular person or community. Anonymous disclosures might have a benefit for those who want to disclose information but at the same time not want to attract unwelcome attention to a community.

There are basically two types of mechanisms for defensively disclosing information. One consists of the traditional methods of publication: scientific, academic, technical, and business journals, and so on. The other mechanism is electronic publication through the Internet. In recent years, many Internet sites have been developed solely for the purpose of defensive disclosure. There are many Internet-based Web sites and databases that contain information on TK.

A community registry could serve as a viable means of defensive disclosure. This would involve placing the registry on the Internet for all to access (this would also include patent examiners during prior art searches), or if a country has a sui generis system in place, limiting outside access to only the patent office.

3.2 *Prior informed consent*

The CBD declares the obligation to obtain prior informed consent for accessing genetic resources. The Bonn Guidelines (2002)[23] further link genetic resources with TK in the obligation to acquire informed consent. Prior informed consent is the approval in advance for the use of one's genetic resources and any associated TK. *Prior* indicates that the approval must come before access is allowed or others use the knowledge. *Informed* means that information is provided on how the resource and/or knowledge will be used. *Consent* means permission to use the resource or knowledge. Sufficient information should be provided to a community, either by the IP office or other party, regarding the aims, risks, or implications of using the knowledge, including its potential commercial value.

Does a community possessing TK legally have the right to prior informed consent if someone accesses its genetic resources and related TK and wishes to use them? The answer: maybe. If the country where the community is located has ratified and implemented the CBD, access to TK should be subject to prior informed consent of the knowledge holders under Article 8(j).

Perhaps an example is the best way to understand how prior informed consent works. Suppose a scientist is traveling in South America and begins to work with a community in the Amazon region. The scientist is particularly amazed when he or she observes the methods used by a local community to process and apply a local plant to heal wounds. The scientist, now aware of the genetic resource and local knowledge of its use, can do one of two things: he or she can do nothing with the knowledge or can use the knowledge. If the scientist does nothing, there is obviously no need to obtain prior informed consent. If the scientist wishes to use the resource or knowledge (publish the knowledge in a journal article, apply for a patent, etc.), he or she must obtain prior informed consent of the appropriate national authorities if that Amazonian country has implemented the CBD.

4. SUI GENERIS PROTECTION SYSTEMS

Sui generis literally means "of its own kind" and consists of a set of nationally recognized laws and ways of extending plant variety protection (PVP) other than through patents. TRIPS itself does not define what a sui generis system is or should be. And although TRIPS does not mention UPOV, it is generally agreed that the UPOV standards meet the requirements for a sui generis system for

plants. However, countries do not have to join UPOV to implement a sui generis system to comply with TRIPS.[24]

A sui generis system might consist of some standard forms of IP protections combined with other forms, or none at all, for genetic resources. For example, a country could provide patent protections for inventions, plant variety certificates (PCV) for plant varieties or just certain varieties, and/or exclude plants from any form of IP protection at all (although this could conflict with TRIPS compliance).

Potentially, a sui generis system could be defined and implemented differently from one country to another. In addition, a sui generis system might be defined to create legal rights that recognize any associated TK relating to genetic resources and promote access and benefit sharing. The government may choose to extend protections to genetic resources and/or knowledge to a community in the form of patents, trade secrets, copyrights, farmers' and breeders' rights, or another creative form not currently established in the IP regime.

In addition, a sui generis system may adopt measures of protection specific to TK in order to nullify inappropriate patents. For example, the Andean Community's Decision 486 states:

patents granted on inventions obtained or developed from genetic resources or traditional knowledge, of which any member state is the country of origin, without presentation of a copy of the proper access contract or license from the community shall be nullified.[25]

A sui generis system may legally acknowledge and protect knowledge related to the use of genetic resources even when it is not officially documented, but instead exists in the form of oral information, and traditional and historic use. Even though protections might be extended here, the government's IP office needs to know about the knowledge or practice in order to enforce protection. Therefore, if a country has some form of a sui generis system in place, it is important for local communities to establish a working relationship with the IP office. In addition, these offices may privately maintain inventories or registries of locally held knowledge, and can assist in its protection. For example, this office can deny a patent application if the knowledge it is based on is already held in the registry.

Under a sui generis system, and as called for by the CBD, any person interested in gaining access to a community's biological resources or knowledge for scientific, commercial or industrial purposes would need to obtain the prior informed consent of the indigenous peoples who possess the knowledge in question unless the knowledge is already in the public domain. This would allow the community to decide on access to and use of its genetic resources and knowledge, with the option to share or not to share them. If consent is granted, the person or persons wishing access to lands held by indigenous communities or a conservation area, its biological resources, and associated knowledge would need to present evidence of this consent to either the IP office or to the proper authority.

5. ACCESS AND BENEFIT SHARING

Access refers to granting permission to enter an area for the purpose of sampling, collecting, and removing genetic or other resources. Benefit sharing refers to all forms of compensation for the use of genetic resources, whether monetary or nonmonetary. This might also include participation in scientific research and development of genetic resources, as well as the sharing the findings of any potential benefits resulting from this work.

Articles 1 and 8(j) of the CBD encourage the equitable sharing of benefits arising from TK for conservation and sustainable use of biological diversity. In benefit-sharing arrangements, all parties share the benefits arising from the use of genetic materials and TK of their uses. For the local community, this involves the sharing of TK and resources with contracting parties and others who wish to use it for research and/or developing new products based on this knowledge. The contracting parties in turn would share any advancements, benefits (including financial), or products that made use of the resources developed from local resources with the local community.

Article 15 of the CBD states that access to genetic resources and any transfer of technology be provided and/or facilitated under fair and mutually agreed-upon terms. This may include types of financial arrangements described later in the CBD (Articles 20 and 21).

Benefits include a wide range of options and often beneficiaries receive more than one type of benefit. They may include:

- **Start-up/upfront benefits.** Payments paid as a lump sum (if a financial arrangement) or delivered (if a cooperative or capacity building project). (These benefits would include equipment such as computer hardware, software, or extraction and screening facilities.)
- **Process benefits.** Derived during the process of research and development. (In addition to financial payments, process benefits may include capacity, expertise, or know-how building, and training through joint research.)
- **Product benefits.** Paid after commercialization of the final product. (These may include royalty payments that may be negotiated according to the contribution of the genetic resource or the amount of or role of local knowledge that was used in creating the final product.)
- **Moral and relation benefits.** Unlike the financial benefits described above, not transferred according to a formalized arrangement, but based on the interaction of the participants.[26]

As an example, let us consider a case in Ecuador. In that country, the Inter-American Development Bank (IDB) and several NGOs have launched a project titled "The Transformation of TK into Trade Secrets." The goal of the project is to catalogue TK and then maintain the database at regional centers, access to which will be safeguarded. Each participating community will have its own file in the database and will not be able to access files of any other community. The collected knowledge will be reviewed, and knowledge that is not common to multiple communities may be negotiated as trade secrets through material transfer agreements (MTA). The benefits from any MTAs are to be split between the Government of Ecuador and the communities that deposited the knowledge in the database. Payments to communities will then be used to finance public projects previously identified by each community.[27]

Contractual agreements[28] are at the heart of any benefit-sharing mechanism. They are legally binding documents between parties. In relation to TK, they are generally used to outline and enforce access and benefit-sharing agreements, as well as trade secrets. Contracts relative to TK may explain or clarify the following points:

- parties to the agreement
- duration of the agreement
- knowledge included in the agreement
- uses of the knowledge
- restrictions placed on the knowledge's use
- restrictions placed on confidentiality
- specifics for benefit sharing

Some types of contracts that might be employed for access and benefit sharing in compliance with the CBD include:

- confidentiality (also known as non-disclosure agreements)
- exclusive licenses
- nonexclusive licensing agreements
- material transfer agreements[29]

The type of contractual arrangement will vary according to the knowledge and/or genetic resources in question, as well as the interests and cultural components related to the knowledge. If considering a contractual agreement, make sure that the selected type of contract corresponds to both the short-term and long-term interests of the community (see also Box 3).

6. LOCATING AND IDENTIFYING TK

In order to protect or preserve TK utilizing the Western framework of IP rights, it is necessary to first locate and identify this knowledge according to the epistemological constructions recognized under this system. TK can be identified in:

- daily activities including, among other things:

  - farming
  - gardening
  - animal breeding and care
  - food and nutrition
  - healthcare and reproductive health
  - water-resource use
  - spiritual and religious activities
  - folklore, songs, poetry, and theater
- community records (Although TK is mostly transmitted by word of mouth, some other forms of record keeping may exist, for example, maps, boundary markers [trees, poles, stones, and so on], drawings, paintings or carvings, and many other forms.)
- people working with the community, such as NGO researchers, academics, scientists, and development specialists who may have been collecting TK
- secondary sources such as journal articles and books, unpublished documents, databases, videos, photos, museums, and exhibits.[31]

An element of TK for which IP protections could potentially apply is called a *knowledge claim.* A TK claim contains three essential components: a genetic resource, a preparation or process, and an end result or product derived from a preparation or process. The genetic resource is typically a plant. The process encompasses the various ways of using the plant for an end result. Processes may include methods of growing, harvesting, extracting, preparing, or applying the plant. The end result is the benefit from using the biological resource and the process. Let's look at an example (Figure 1).

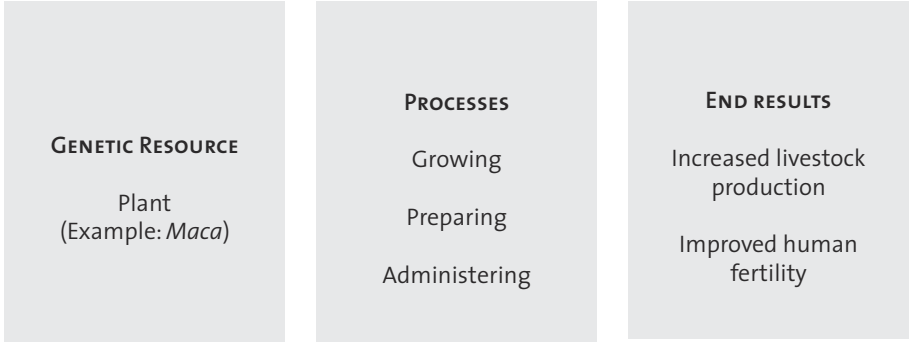
The three categories (Plant, Process, Product) can be combined in a variety of ways producing several claims. For example, from the simple figure below, it is possible to deduce six claims of process methods involving the plant:

- growing *maca* to cause an increase in livestock reproduction
- preparing *maca* to cause an increase in livestock reproduction
- administering *maca* to cause an increase in livestock reproduction
- growing *maca* to improve human fertility
- preparing *maca* to improve human fertility
- administering *maca* to improve human fertility

7. IDENTIFYING WHO HOLDS THE KNOWLEDGE

After identifying a TK claim, the next step is to determine whom the knowledge holders and stakeholders are for the claim. The knowledge holders are the people who hold and/or use the knowledge, and stakeholders are the people in the community with a direct interest in the knowledge. When making a decision in relation

Figure 1: Three Components of a TK Claim



to a specific knowledge claim, one must consult all of the stakeholders of that claim (which is often the entire community and/or other communities as well) before making a final decision about how any IP rights should be applied.

TK can either originate within a community or enter a community from the outside. If the knowledge is not originally from within the community in question, then it may not be subject to any IP rights and may already be part of the public domain. If the knowledge is from within the community, then the next step is to determine who holds the knowledge. The holder(s) of the knowledge can be an individual, multiple individuals, or the community as a whole.

The next step is to determine who uses or has access to the knowledge. Knowledge claims can either be held or practiced by no one, an individual, multiple individuals, a community, or people outside the community.

Any potential IPR options will depend on how many people are aware of the knowledge and who these people are. Based on these variables, a knowledge claim can fit into on of three groups:

1. Known and used by an individual
2. Known and used by several individuals or a community
3. Diffused broadly and in the public domain.

Figure 2 can assist in determining who holds the knowledge and who the stakeholders are in order for help in deciding which options to pursue for an identified knowledge claim.[32] The dashed box in the figure represents knowledge that may fall within IP rights protections and that is not part of the public domain. If the knowledge crosses outside the box, the knowledge may already be in the public domain (with or without prior informed consent[33] and with no options for IP rights protection [see Section 3.2]).

8. IDENTIFYING IP OPTIONS

8.1 *Determining cultural aspects*

The scientific aspect of TK is only one aspect of a larger culture of knowledge. For this reason, culture cannot be ignored when applying IP rights to TK. Cultural aspects that are important to TK are described below under six general categories. Each category should be considered independently, and in combination, when evaluating the place of a specific claim in its cultural context and in the IP rights regime.

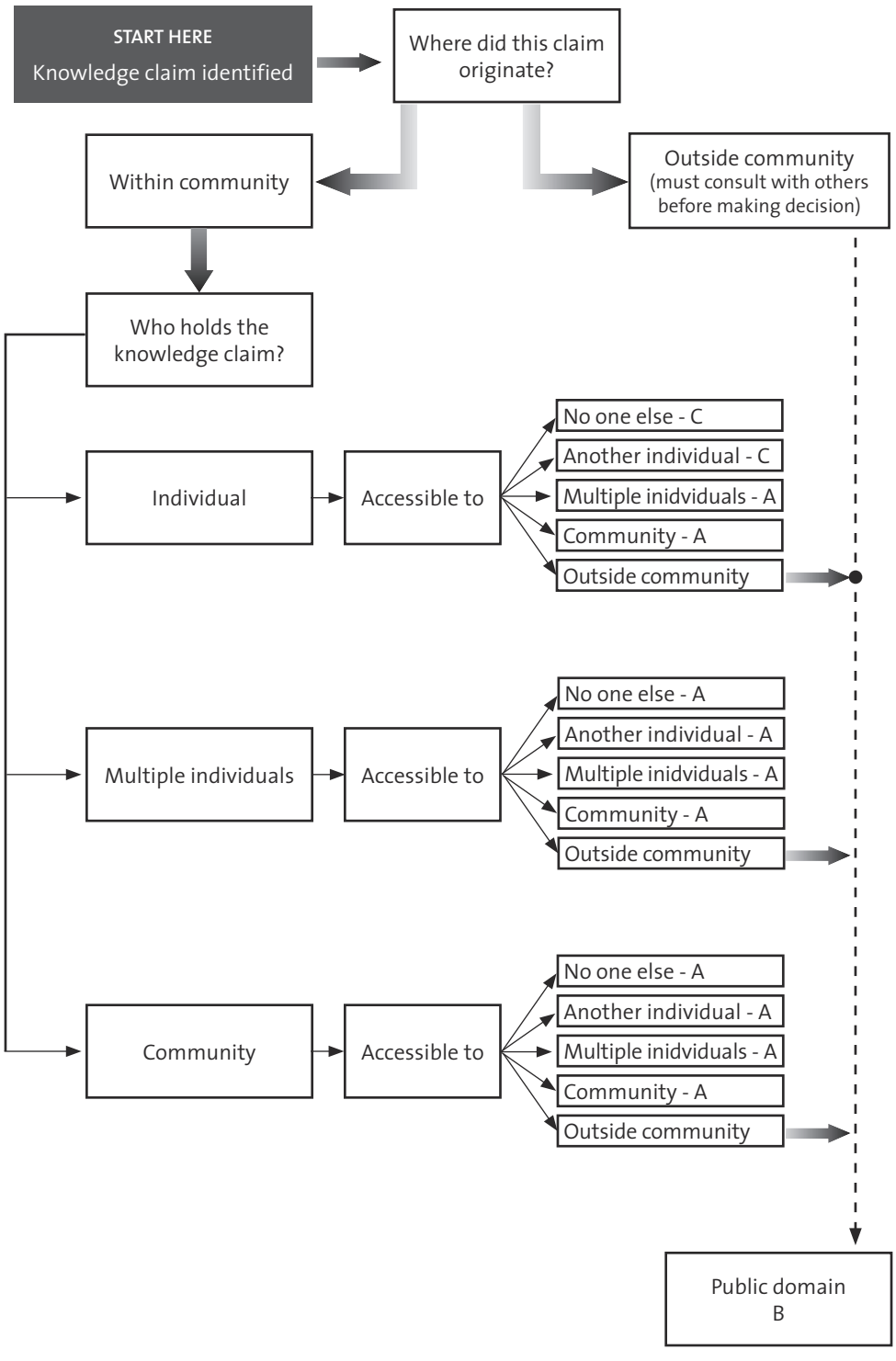
1. **Spiritual.** knowledge that not only has a useful or functional purpose but also some form of spiritual, religious, or sacred importance
2. **Subsistence.** knowledge necessary for the basic survival of the community, including knowledge used for food production or any knowledge vital for life and survival
3. **Economic.** knowledge with strong ties to the economic survival or benefit of the TK stakeholders
4. **Traditional secret.** knowledge that is held as a secret among the community (Disclosing knowledge within this category to the general public would be culturally inappropriate.)
5. **Medicinal.** knowledge used to cure or prevent medical ailments within a community
6. **Historic.** knowledge that is of historic importance to the community

8.2 *Determining community goals*

When evaluating a knowledge claim and determining potential options for protection, the goals and interests of the community are important to consider. Five categories may be used for determining community goals for a claim:

1. **Profit.** commercializing and receiving financial gains or other economic benefits from TK
2. **Dissemination for public good.** sharing TK in order to benefit others (This goal is particularly applicable to TK with medicinal or agricultural uses.)
3. **Avoiding exploitation.** preventing the harming or usurpation of culture and environment (Control over knowledge, the way it is used, and its concurrent effects on the culture and environment are important to the TK stakeholders.)

Figure 2: Identifying Who Holds the Knowledge



4. **Avoiding inappropriate IP claims.** avoiding IP claims on community knowledge or resources by outsiders (The protection of moral and material interests is of primary importance.)

8.3. *Preserving TK above other interests or desires*

Once TK has been identified and the cultural and goal-oriented dimensions of the knowledge explored, stakeholders should cross-reference these cultural values and goals with relevant IP options available in a given country.

9. CONCLUSIONS

This chapter explains possible IP mechanisms that might be applied to protect TK and biological resources. Our experience shows that it has served more as an educational resource to alert TK holders to the possible risks of others seeking IP rights protection than as a resource for seeking IP rights protections themselves. Yet, it is true that over the past several years a growing number of TK holders have started to explore the potential use of IP protections. Still, for many reasons, TK remains elusive to current IP laws.

Local and indigenous peoples' management and protection of IP rights associated with their biological resources and TK remain a challenge. In order to address this challenge, it will be necessary to properly recognize and protect TK and also to employ global mechanisms for equitable benefit sharing. In the more-immediate term, existing mechanisms of IP rights protection will need to be effectively utilized in order to confer adequate protection and benefit sharing. However, in the longer term, changes to both the domestic and global IP regimes might be required. Yet, regardless of the exact type of IP rights protection employed, the end result must always be aimed toward a balance, that is, to better protect and provide equitable benefit to the originators of that TK while serving the broader public interest. In other words, access, development, and distribution must be balanced against equitable benefit sharing, sustainable development, and conservation. ■

ACKNOWLEDGMENTS

The authors would like to thank the following people and organizations for their support and assistance throughout the creation of this chapter: the secretariat of the World IP Organization's Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore; Merida Roets, president of *ScientificRoets* (South Africa) and former AAAS Science Radio Fellow; participants from the AAAS Roundtable on Traditional Knowledge at the Fifth Session of the WIPO IGC on Genetic Resources, Traditional Knowledge and Folklore, 14 December 2002; Rosemary Coombe, Tier One Canada Research Chair in Law, Communication and Cultural Studies at York University in Toronto; Michael Gollin, project legal consultant and attorney at Venable, LLP; Matthew Zimmerman, computer specialist at the AAAS Science and Human Rights Program. This publication was made possible in part from grants provided by the Center for the Public Domain and the Richard and Rhoda Goldman Fund.

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