RFS

ISSN 2695 6462

## ESTUDIOS

# Can intellectual property be used to halt global biodiversity loss?

**Andrea Alunni**[1]

**Abstract:** Biodiversity loss is the single biggest negative consequence from environment degradation. Access and benefit sharing (ABS) – stipulated by the Convention on Biological Diversity (CBD) and established under Nagoya protocol (NP) – is a policy approach that links access to genetic resources (GR) and traditional knowledge (TK) to the sharing of monetary and nonmonetary benefits. This article examines how the ABS has become the principal instrument embraced by the international fora to prevent further biodiversity loss by avoiding GRs extinction and/or degradation, often due to the misuse and misappropriation of TK associated to GR management.

The objective of this research is to analyse the process in which traditional knowledge associated to the management of genetic resources (TK–GR) came onto the Intellectual Property (IP) agenda and to verify whether ABS can effectively regulate the access to the world's GRs while contributing to the conservation of biological diversity and the sustainable use of its components in a way that is acceptable to all stakeholders. The research was carried out in **two parts:**

**The first**, explores the literature that outlines the evolution of the IP policy debate in which the IP–TK–GR linkage was recognised as having significant implications to avoid biodiversity loss by preserving TK holders' role in a rapid evolving biotechnology innovation environment. This was conducive to **the second part** which assesses the governance in relation to TK–GR protection together with the challenges and opportunities that international institutional and political frameworks face to support ABS adoption across countries. A practical example illustrates how indigenous peoples and local communities' skills can be embedded in technology transfer best practices to effectively adopt ABS to produce new knowledge, innovation and prosperity from joint research and cooperation between traditional and modern scientists.

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[1] Università degli Studi di Perugia – C.I.R.I.A.F.–SSTAM, https://orcid.org/0000–0001–8080–3695, andrea.alunni@hotmail.com.

**Keywords:** *Biodiversity; Convention on Biological Diversity (CBD); Indigenous Peoples and Local Communities (IPLC); Traditional Knowledge (TK); Genetic Resources (GR); traditional knowledge associated to the management of genetic resources (TK–GR); Intellectual Property (IP); Patents Disclosure Requirement (PDR); Sui Generis; innovation; Access–Benefit–Sharing (ABS); Nagoya Protocol; International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).*

**Fecha de recepción:** 11 de enero de 2022.

**Fecha de admisión definitiva:** 20 de julio de 2022.

**¿Puede utilizarse la propiedad intelectual para frenar la pérdida de biodiversidad a nivel global?**

**Resumen:** La pérdida de biodiversidad es la principal consecuencia negativa de la degradación del medio ambiente. El acceso y la participación en los beneficios (APB), estipulado por el Convenio sobre la Diversidad Biológica (CDB) y establecido en el Protocolo de Nagoya (PN), es un enfoque político que vincula el acceso a los recursos genéticos (RG) y a los conocimientos tradicionales (CT) con la participación en los beneficios monetarios y no monetarios. Este artículo examina cómo el APB se ha convertido en el principal instrumento adoptado por los foros internacionales para prevenir una mayor pérdida de biodiversidad evitando la extinción y/o degradación de los RG, a menudo debido al mal uso y la apropiación indebida de los conocimientos tradicionales asociados a la gestión de los RG.

El objetivo de esta investigación es analizar el proceso por el cual los conocimientos tradicionales asociados a la gestión de los recursos genéticos (CT-RG) entraron en la agenda de la Propiedad Intelectual (PI) y verificar si el APB puede regular eficazmente el acceso a los RG del mundo, contribuyendo

**La propriété intellectuelle peut–elle être utilisée pour enrayer la perte de biodiversité mondiale?**

**Résumé:** La perte de biodiversité est la conséquence négative la plus importante de la dégradation de l'environnement. L'accès et le partage des avantages (APA) –stipulé par la Convention sur la diversité biologique (CDB) et établi par le protocole de Nagoya (PN)– est une approche politique qui lie l'accès aux ressources génétiques (RG) et aux connaissances traditionnelles (CT) au partage des avantages monétaires et non monétaires. Cet article examine comment l'APA est devenu le principal instrument adopté par les forums internationaux pour prévenir une nouvelle perte de biodiversité en évitant l'extinction et/ou la dégradation des RG, souvent due à l'utilisation abusive et au détournement des savoirs traditionnels associés à la gestion des RG.

L'objectif de cette recherche est d'analyser le processus par lequel les connaissances traditionnelles associées à la gestion des ressources génétiques (CT–RG) ont été inscrites à l'ordre du jour de la propriété intellectuelle (PI) et de vérifier si l'APA peut réglementer efficacement l'accès aux RG du monde tout en contribuant à la conservation de la diversité

al mismo tiempo a la conservación de la diversidad biológica y al uso sostenible de sus componentes de una manera aceptable para todas las partes interesadas. La investigación se llevó a cabo en **dos partes:**

**La primera**, explora la literatura que describe la evolución del debate sobre políticas de PI en el que se reconoció que el vínculo PI-TK-GR tiene implicaciones significativas para evitar la pérdida de biodiversidad preservando el papel de los titulares de los CT en un entorno de innovación biotecnológica en rápida evolución. Esto condujo a **la segunda parte**, en la que se evalúa la gobernanza en relación con la protección de los conocimientos tradicionales y los derechos de propiedad intelectual, así como los retos y las oportunidades a los que se enfrentan los marcos institucionales y políticos internacionales para apoyar la adopción del APB en los distintos países. Un ejemplo práctico ilustra cómo las competencias de los pueblos indígenas y las comunidades locales pueden integrarse en las mejores prácticas de transferencia de tecnología para adoptar eficazmente el APB con el fin de producir nuevos conocimientos, innovación y prosperidad a partir de la investigación conjunta y la cooperación entre científicos tradicionales y modernos.

**Palabras clave:** *Biodiversidad; Convenio sobre la Diversidad Biológica (CDB); Pueblos Indígenas y Comunidades Locales (PICL); Conocimientos Tradicionales (CT); Recursos Genéticos (RG); conocimientos tradicionales asociados a la gestión de los recursos genéticos (CT-RG); Propiedad Intelectual (PI); Requisito de Divulgación de Patentes (RDP); Sui Generis; innovación; Acceso-Beneficio Compartido (APB); Protocolo de Nagoya; Tratado Internacional sobre los Recursos Fitogenéticos para la Alimentación y la Agricultura (TIRFAA).*

biologique et à l'utilisation durable de ses composants d'une manière acceptable pour toutes les parties prenantes. La recherche a été menée en **deux parties:**

**La première**, explore la littérature qui décrit l'évolution du débat sur la politique de la PI dans lequel le lien PI–CT–RG a été reconnu comme ayant des implications significatives pour éviter la perte de biodiversité en préservant le rôle des détenteurs de TK dans un environnement d'innovation biotechnologique en évolution rapide. Cette constatation a été propice à **la deuxième partie**, qui évalue la gouvernance en matière de protection des savoirs traditionnels et des droits de propriété intellectuelle, ainsi que les défis et les opportunités auxquels les cadres institutionnels et politiques internationaux sont confrontés pour soutenir l'adoption de l'APA dans les différents pays. Un exemple pratique illustre comment les compétences des peuples autochtones et des communautés locales peuvent être intégrées dans les meilleures pratiques de transfert de technologie afin d'adopter efficacement l'APA pour produire de nouvelles connaissances, de l'innovation et de la prospérité à partir de la recherche conjointe et de la coopération entre les scientifiques traditionnels et modernes.

**Mots clés:** Biodiversité; Convention sur la diversité biologique (CDB); Peuples autochtones et communautés locales (PACOL); Connaissances traditionnelles (CT); Ressources génétiques (RG); Connaissances traditionnelles associées à la gestion des ressources génétiques (CT–RG); Propriété intellectuelle (PI); Exigence de divulgation des brevets (DDP); Sui Generis; innovation; Accès–Partage des Avantages (APA); Protocole de Nagoya; Traité international sur les ressources phytogénétiques pour l'alimentation et l'agriculture (TIRPAA).

## 1. Introduction

Biodiversity loss is the biggest single negative consequence from environment degradation. Traditional knowledge provides the bedrock for successful ways of subsisting in what are often hostile natural environments. Indeed, there is growing recognition that traditional knowledge, technologies and cultural expressions are not just old, obsolete and maladaptive as they can rather be highly evolutionary, adaptive, creative and even novel. Moreover, tradition often represents the bond strengthening social cohesiveness and communities cultural identity.

Considering that only in exceptional cases, if any, human societies are totally isolated or self–sufficient in all respects, however, indigenous and traditional societies not only consume knowledge–based and other goods that are produced locally but also give, receive, share, own and exchange them with others, including those from modern societies. The present study examines recent trends and proposals for the protection of traditional knowledge to offer a better understanding of the proper role of intellectual property in a knowledge–based economy. In modern societies, identifying, registering and protecting intellectual property rights (IPR) has become one of the key drivers of business competitiveness in international trade.

While intellectual property is today's competitive instrument in global markets, exploiting and effectively protecting it is complex and difficult. Not all knowledge, innovation and creation lend themselves to the existing models of industrial and post–industrial societies and more specifically the IP system. In this context, the value and usefulness of traditional knowledge (TK) in the preservation of natural ecosystems, seeds domestication, production of traditional food, use of alternative medicine and, more recently, biotechnology has been widely recognized. However, there is much debate on how best to protect such a knowledge system from *biopiracy* considering its multifaceted nature as well as its implications for various policy issues and sustainable development in general.

This research provides an overview of the main arguments and proposals created by developing and developed countries in the discussions organized by the Convention on Biological Diversity (CBD), World Intellectual Property Office's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO–IGC) and the International Treaty of Plants Genetic Resources for Food and Agriculture (ITPGRFA) with respect to the protection of TK. It aims at responding the research question 'Can intellectual property be used to halt global biodiversity loss?' and aims to clarify whether the conventional agreed IP instruments designed to protect intellectual knowledge can serve the purpose of protecting

biodiversity by avoiding TK–GR misappropriation. In this effort, it also examines how the international community is supporting the compensation mechanism for TK holders when a TK–based patent is successfully granted and able to yield monetary and non–monetary benefits.

The research was carried out in **two parts. The first**, explores the literature that outlines the evolution of the IP policy debate in which the IP, TK and GRs relationship was recognised as having significant implications to avoid biodiversity loss by preserving Indigenous Peoples and Local Communities' (IPLC) role in a rapid evolving biotechnology innovation environment. This was conducive to **the second part** which assesses the governance in relation to TK–GR protection together with the challenges and opportunities that international political frameworks offer to support ABS–Nagoya Protocol adoption across countries.

The bulk of literature available indicates that IPRs have never been more economically and politically important or controversial than they are today in a knowledge–based economy, where understanding how to manage intellectual assets is essential to make informed decisions by policy makers in almost all areas of human development. This paper examines prevailing justifications for TK protection, identifies plausible reasons to pursue legal solutions to the lack of TK protection and verifies the advancements in achieving international consensus. In particular, this consensus is needed to achieve globally accepted laws and policies to combat "*biopiracy*" in order to stop individuals and corporations misappropriating the genetic resources, traditional knowledge and technologies of the developing countries. Findings indicate that the ABS regime offered by the CBD has all the potential to become an effective international instrument to regulate access to TK–GR while preventing biodiversity loss. However, for this to be doable, a trustful and meaningful cooperation model between traditional and modern scientists still needs to be devised to encourage compliance with Nagoya Protocol obligations and, hence, full adoption.

Objections to traditional knowledge protection are not necessarily done through bad faith and deserve a considered response. Opposing views to TK protection argue that the creation of a new TK protection regime would directly represent the removal from the public domain of a substantial part of practical knowledge relevant to the biosphere (including solutions to health, agricultural and environmental problems affecting many people) and that keeping it in public domain favours everybody.

Opposing views also persist on the impacts of protecting TK via IPRs on a country's development prospects; some argue that in a modern economy, the minimum standards will bring benefits to developing countries by creating the incentive structure

necessary for knowledge generation and diffusion, technology transfer and private investment flows. Others counter that intellectual property, especially some of its elements such as the patenting regime tool 'Patent Disclosure Requirement' used by the Convention on Biological Diversity (CBD) to protect TK associated to genetic resources, will adversely affect the pursuit of innovation. Looking at a successful project from Peru, allowed practical recommendations including the need to increase awareness about the (hidden) benefits that the full adoption of a CBD mechanism could bring research and innovation via fruitful cooperation between traditional and modern scientists, researchers and innovators on their own rights and culture. For this, an example is offered to illustrate how indigenous peoples and local communities' skills can be embedded in technology transfer's best practices to effectively adopt an ABS regime to produce new knowledge, innovation and prosperity from joint research and cooperation between traditional and modern scientists.

In terms of environmental governance, the most substantial negotiations seem now to be those taking place at WIPO. They have reached the point of producing (but not agreeing upon) a set of draft provisions to facilitate the ABS regime implementation, as the most promising sui generis regimes, such as ABS, to contrast misappropriation via disclosure of origin. This research's findings also indicate that the "patent disclosure requirement" (PDR) is the dominant link between the IP system and CBD, reason why PDR has become a collective term for certain requirements to be incorporated into patent law for the TK–GR protection, as it consists in requiring patent applicants to submit with their official application documentation from provider countries proving that TK and GR, where opportune, can be accessed in accordance with the ABS regulations which contemplate specific obligations such as prior informed consent (PIC) and mutually agreed terms (MAT) that, once accepted and adopted by providers and the recipients, lead to the compliance of CBD Article 8(j) on the knowledge, innovations and practices of indigenous and local communities.

It is hoped that this research will help facilitate the emergence of a critical mass of well–informed stakeholders in developing countries –including decision makers, negotiators from both public and private sector– in order to define an acceptable pathway to 'Sustainable Development' that in accordance with the UN Human Development Index (HDI) encourages TK protection sustained by both the IP and non–IP options. For most, findings indicate that such a pathway could be represented by the sui generis regime presented by the Convention on Biological Diversity (CBD) particularly with regard to current discussions and negotiations of the protection and promotion of traditional knowledge at varying levels.

## 2. Part I: Intellectual property – Traditional knowledge – Genetic resources: an ongoing policy debate

To understand the state–of–the–art of global environmental sustainability it is essential to establish the drivers of global biodiversity loss both at terrestrial and marine levels. Literature [1] indicates that main drivers are: land clearing for agriculture; wildlife poaching; overfishing and by–catch; invasive species; and climate change. Particular attention will be dedicated to the modern food system, as evidence shows [2], that it is the primary driver of biodiversity loss, with expansion and intensification of agriculture alone being the identified threat to 24,000 of the 28,000 (86%) species at risk of extinction. Experts [3, 4] contend, though, that within the global land and marine–based habitats decline, **Indigenous and Local Communities–managed areas represent the only exception**. In light of it, this research posits: to avoid further biodiversity loss it is necessary to preserve the role of these communities as natural custodians of global natural habitats and the traditional knowledge they have used for generations to preserve, maintain and enrich natural habitats in a sustainable manner.

A recent analysis [5] shows that approximately 60% of total global biodiversity loss for bird and mammal species has occurred in just seven countries: Indonesia, Malaysia, Papua New Guinea, China, India, Australia and the United States. Research findings [6] elucidate that while much species loss has taken place in specific locations, it is often driven by global systems, with choices and actions taken in one place having effects far away. This leads to a question that often underlines the political debate: is biodiversity loss a developmental issue? In the effort to identify causes, consequences and measures for action.

The World Bank [7] argues that global decline in biodiversity and ecosystem services is certainly a development issue because that is likely to affect the poorest countries the most, contending that loss of ecosystem services has substantial negative effects on developing countries food security, water supply, livelihoods, and output of many economic sectors. To put it into context, the Bank estimates that 75% of annual crop output is directly attributable to animal pollination, worth circa US$235 billion to US$577billion and projects that if vital ecosystem services (including those provided by forests, fisheries, and pollinators) collapse, annual GDP could forego 9.7% in Sub–Saharan Africa and 6.5% in South Asia by 2030, threatening thus developing countries with heavier development gains.

Other sources [8] sustain that biodiversity crisis also a development crisis, emphasising that both crises bring higher exposure to the developed world productive industry

as it makes private sector investments riskier, for example, in the effort to tackle the carbon storage issue. A pragmatic picture of this interrelated crisis, is presented by the Swiss Re Institute who analysed the global Biodiversity and Ecosystems Services (BES) state of developed and developing countries [9]. The analysis found that over half (55%) of global GDP, equal to USD 41.7 trillion, is dependent on high–functioning biodiversity and ecosystem services and that a staggering fifth of countries globally (20%) are at risk of their ecosystems collapsing due to a decline in biodiversity and related beneficial services. It also found that 39 countries have ecosystems in a fragile state on more than a third of their land, and that among those with the lowest BES are Malta, Israel, Cyprus, Bahrain and Kazakhstan. As a conclusion, the Institute confirms that loss of biodiversity leads to financial risks and threatens the availability of ecosystem services; recognising that developing countries heavily dependent on agricultural sectors are the most susceptible to BES shocks, although G20 economies such as South Africa and Australia are part of the top rankings of fragile BES and major economies in Southeast Asia, Europe and the United States being exposed to BES decline.

The above highpoints the profound impact of biodiversity on the various aspects of human existence (from culture and health to financial opportunities) to sustain wealth of communities' livelihoods and implies that rekindling traditional knowledge related to food security, health of populations and livelihood production dependent on BES becomes not only an urgent need but also an opportunity. In the following sections of this documents, the issue of finding pathways for rekindling traditional knowledge will be appraised.

## *2.1. Finding pathways for rekindling traditional knowledge*

Management of Biodiversity Economic Systems (BES) in the context of multistakeholder initiatives and through co–engaged participation of traditional knowledge holders provides an important opportunity for developing new, more flexible and adaptive approaches to engage with complex systems in the situations of quick change, uncertainties and limited resources [10]. It also suggests that the contribution of **traditional knowledge** (TK) as the foundational value of biodiversity and resilience of natural ecosystems becomes especially evident in cases where ongoing economic and financial struggle is combined with socio–political circumstances that eliminate or severely diminishes knowledge of traditional practices (by either emphasising other forms of knowledge or eliminating TK as an inferior form of knowing). Experts [11] attribute to traditional knowledge real scientific value and technical qualities to support livelihood production dependent on ecosystem services while

improving global biocapacity balance, reason why representatives of the United Nation Permanent Forum for Indigenous Issues [12] argues that lack of traditional knowledge appreciation cannot be any longer overlooked while searching for pathways to strengthening biodiversity and ecosystem services (BES).

To keep tracking on global ecological balance, the United Nations measures 'Sustainable Development' using an index based on two overarching indicators [13]. **The first**, the UN' Human Development Index (HDI), measures how countries' achieves longevity, access to education, and income considering that an HDI higher than 0.7 is "high human development", which is currently achievable by developed countries. **The second,** is the ecological footprint, which measures whether humanity lives within the means of nature and, interestingly, this is currently achievable by countries rich in biodiversity where indigenous communities are actively managing natural ecosystems using their traditional knowledge. The indicators pursuit is to explain that at the base of global ecological footprint is the question of whether humanity lives within the means of nature, which implies that the two indicators are complementary to achieve 'sustainable development' in a scenario of global habitat decline and shows how much more we need to "think inside the box.".

Combining these two indicators provides clear minimum conditions for global sustainable human development and that when the ecological footprint of a population exceeds the biocapacity of the area available to that population, an ecological deficit occurs; meaning that a national ecological deficit entails that the nation is not only importing biocapacity that cannot afford through trade but that it might be also liquidating its national ecological assets or emitting carbon dioxide waste into the atmosphere. In such a case, traditional knowledge can be engaged with complex systems [13] to share with scientists the best practices and pathways that indigenous communities have already found and used to manage natural ecosystems, thereby assuming a crucial role in the global quest to achieve a biocapacity balance. Such traditional knowledge role can be considered equivalent to that played by industrialisation to keep high the first UN indicator used by the UN 'Sustainable Development' to measure longevity, access to education, and income.

A practical way of looking at this, is shown in the table below where current trends of global biocapacity are shown for the top ten countries with higher biocapacity **deficit** (among which are some of the high countries in the world) against the top ten with higher biocapacity **reserve** (mostly made of developing countries, including some of the poorer in the world). This indicate that a concrete opportunity exists for cooperation among these two categories of countries to find workable solutions to achieve biocapacity balance.

| COUNTRIES WITH BIOCAPACITY RESERVE<br>*PERCENTAGE THAT BIOCAPACITY EXCEEDS ECOLOGICAL FOOTPRINT* | | COUNTRIES WITH BIOCAPACITY DEFICIT<br>*PERCENTAGE THAT ECOLOGICAL FOOTPRINT EXCEEDS BIOCAPACITY* | |
|---|---|---|---|
| French Guiana | 4,810% | Singapore | 10,400% |
| Suriname | 2,520% | Réunion | 2,540% |
| Guyana | 2,030% | Israel | 2,440% |
| Gabon | 869% | Barbados | 2,030% |
| Congo | 754% | Cyprus | 1,770% |
| Uruguay | 641% | Bahrain | 1,660% |
| Central African Republic | 524% | Kuwait | 1,480% |
| Bolivia | 358% | United Arab Emirates | 1,470% |
| Brazil | 233% | Qatar | 1,450% |
| Paraguay | 228% | Saudi Arabia | 1,110% |

Source: Global Footprint network. (2022).

A plausible way to achieve workable solutions should contemplate **unlocking the potential of traditional knowledge to help modern scientific society address the challenges such as climate change and sustainable agriculture and to find new pathways for sustainable development**. The fact that global biodiversity is declining at an unprecedented rate but at significant slower rate with **on lands governed by indigenous peoples** [14] demonstrates their success as stewards of their natural environment; where biodiversity describes genetic diversity within and between species and is integral to the health and resiliency of ecosystems and makes imperative for indigenous knowledge to play an integral role in the fight to protect our sacred global biome.

In order to establish a workable pathway to protect biodiversity from further decline and extinction, in the following paragraphs this research examines linkages between biodiversity, traditional knowledge and poverty reduction to sanction evidence where local communities have time and again proved that their knowledge and practices outweigh the risks associated with technology–based interventions to achieve sustainable development either as a macroeconomic component or as a micro–enterprise led development.

## *2.2. Traditional knowledge protection—An opportunity to improve environmental conservation and management*

The preservation of natural ecosystems is today a common objective for developed and developing countries interested to keep ecological footprint lower (first UN indicator for sustainable development above) by making reasonable management areas of biologically productive land and water to produce resources they consumed using both prevailing technology and traditional management practices, including traditional knowledge associated with natural ecosystem management.

The UN suggests [13] that measuring ecological footprint of all nation provides an idea of the "Number of Earths" required to support humanity. Addressing the current scenario, instead, consists in making every effort to keep global biocapacity balanced in practical terms. Rekindling traditional knowledge seems to abridge this opportunity, as clearly stated by the UN Forum for Indigenous Issues (UNFII) when explaining how can the indigenous peoples' traditional knowledge benefit everyone, as follows:

> *'Indigenous peoples' traditional knowledge can offer valuable responses to climate change, food insecurity, reducing inequalities and other challenges that we are trying to resolve through the Sustainable Development Goals (SDG). Traditional knowledge offers tremendous opportunities in such areas as land management, conservation, and scientific, technological and medical research. The 2030 Agenda for Sustainable Development makes six specific references to indigenous peoples. These include a commitment to double the agricultural output of indigenous smallscale farmers and a commitment to ensure equal access to education for indigenous children. Countries have also committed to empower and engage indigenous peoples in the implementation of the Sustainable Development Goals.*

Yet, traditional knowledge is rapidly disappearing. UNESCO estimates that at least 43% of 6,000 languages spoken in the world are endangered most if not all of these are Indigenous languages and represents a great loss of TK [14]. Around a quarter of the world's languages have fewer than a thousand remaining speakers, and linguists generally agree in estimating that the extinction of at least 3,000 of the 6,909 languages listed by Ethnologue, or nearly half, within the next century is virtually guaranteed under present circumstances. Gaps in human development, scant economic opportunities for Indigenous Peoples, education systems that do not respect its value or undermine traditional cultures, inadequate land rights, urbanization, the migration of youth, the passing of elders, and a lack of respect for traditional knowledge as a knowledge system are among the factors causing this loss. Addressing these threats is complex. There is little doubt that the conservation of cultural diversity and the retention of traditional knowledge are key issues for

a world embarked on a path of globalization and cultural homogenization at a speed and rate of acceleration scarcely conceivable.

Inclusion of indigenous and traditional knowledge in environmental management is thus an **opportunity** to learn from generations of careful observation, reinforcing at the same time the right of indigenous peoples to use, access and act as stewards of their traditional lands. Country experiences [10] show that environmental governance is strengthened by a growing number of **collaborative initiatives** aiming to include the perspectives and knowledge of indigenous peoples to improve environmental conservation and management.

### *2.3. Recognising that TK protection, as a pillar of sustainability, needs a roadmap*

**The first step:** acknowledging that TK deserves the help of modern science for its protection **as indigenous and local communities hold a recognised capacity to preserve biodiversity.** This is best said in the words of UN Economic and Social Council:

> *A product of learning through experience and oral traditions passed over centuries, indigenous traditional knowledge is generated, transmitted, and strengthened through rituals, metaphors, proverbs, songs, oral history, human interactions, ceremonies, languages, experiences and practices. Protecting indigenous languages is fundamental to preserving traditional knowledge. It is through indigenous languages that this knowledge is generated and transmitted. Yet today, close to 2,700 languages are estimated to be in danger of disappearing forever. If we lose them, we also risk losing invaluable knowledge that could have provided answers to some of the world's greatest problems. Paradoxically, modern technology can help us preserve and revitalize indigenous knowledge and languages and pass them on to future generations. Partnerships between indigenous peoples and Governments, the UN system, businesses and, increasingly, the communications sector, can help to harness modern technologies to preserve the priceless ancient knowledge.* (Chandra Roy–Henriksen, Chief of the Secretariat of the UN Permanent Forum on Indigenous Issues, 2022)

**The second step:** accepting that indigenous and traditional knowledge triggers actions in support of biodiversity conservation and relevant genetic resources should go beyond its simple validation in the context of conventional science–based approaches (for example, via conventional Patent System eligibility criteria). Traditional and indigenous knowledge related to biodiversity is central to elucidating its status and trends and for developing plausible scenarios based on **community participation** with regard to the way biodiversity is conserved and used. For indigenous peoples, sustainability is a necessity, for without it our global wealth is at risk. Traditional ecological knowledge and practices have been so successful that, although indigenous

lands account for less than 22 percent of the world's land area, their traditional territories are home to approximately 80% of the world's biodiversity [15]. This should lead to a growing appreciation of the value of traditional knowledge (in this specific case traditional ecological knowledge) in promoting sustainable land management and scientific discovery and in providing environmental data to support climate adaptation strategies.

In fact, traditional knowledge has been being recognized as complementary to modern science in supporting sustainable land and resource management as it is the product of indigenous peoples' deep understanding of their environment, which has evolved over many generations. Despite a history of marginalizing indigenous groups, developed countries have progressively recognized the strength of indigenous knowledge in managing the natural environment. Australia, for example, started in the 1990' with the establishing of 75 indigenous protected areas where traditional management practices, such as the ritualized burning of vegetation to improve soil productivity, are both culturally and ecologically important. [15]. Likewise, in developing countries traditional knowledge often helps to unveil valuable information about the intricacies of environmental systems. By learning from centuries of careful observation and understanding the traditional practices of indigenous peoples, for example, scientists can advance their understanding of natural systems. This is the case of the indigenous farmers of the Bolivian and Peruvian Andes whom successfully forecast weather patterns by observing the size and brightness of the Pleiades star cluster. By observing the practices of these indigenous farmers, scientists discovered a link between El Niño and tropospheric cloud cover that scientists were not previously aware of. This discovery, and many others resulting from the traditional knowledge of indigenous peoples, demonstrates the important role that traditional ecological knowledge has to play in our collective understanding and management of the environment.

**The third step:** assuming **the socio–economic prosperity that TK protection entails cannot be achieved via biopiracy.** TK protection is motivated by the increased commercial exploitation of traditional knowledge by others which raises the **need for legal TK protection** against misuse and misappropriation. Advocates of TK protection consider that the kind of socio–economic impact that TK protection can have on the prosperity of the global community (not only on indigenous peoples and local communities) include *prevention of "biopiracy"*.

To better illustrate biopiracy in the biodiversity loss context, following are listed acts that have been considered as acts of biopiracy of traditional knowledge (TK):

- The unauthorised use of TK only found among indigenous peoples and local communities (IPLC).
- The unauthorised use of TK acquired by deception or failure to fully disclosure the commercial motive behind the acquisition.
- The unauthorised use of TK acquired on the basis of a conviction that all such transactions are inherently exploitative ("all bioprospecting is biopiracy").
- The commercial use of TK on the basis of a literature search Patenting.
- The patent claims TK in the form in which it was acquired, a refinement of the original TK or when the patent covers an invention based on TK.

**The fourth step:** admit that **lack of TK protection bolsters global impoverishment.** Whereas biodiversity, traditional knowledge and poverty is a linkage that seems to portray indigenous and local communities in developing countries, evidence shows that this ancient knowledge and practices often outweigh the risks associated with technology–based interventions to achieve sustainable development models to preserve biodiversity further deterioration and/or risk of extinction by modern scientists [10]. Lack of TK protection for its real scientific value and technical qualities causes traditional knowledge to be widely overlooked and considered narrow from a cultural, scientific and innovation perspective. This trend is aggravated by the fact that dissemination of traditional knowledge to the younger generation is not common, to the point of being almost non–existent. These four steps here considered are potential guidance for mainstream education, training, research, science, innovation and technology transfer to promote of successful Indigenous experiences as prospect solutions to old and new problems.

The traditional knowledge of indigenous and local communities' protection is today a need motivated by the increased commercial exploitation without the consent of TK holders and, although some existing IP laws have been successfully used to protect against some forms of *piracy*, IP system limitations in meeting all the needs and expectations of TK holders are currently materialised in two significant barriers to overcome: **one**, to address the TK protection issue to an international dimension, as it involves many areas of law and policy that often **goes well beyond intellectual property rights** (including, in the interplay of property rights, the practice of social norms, the operation of markets, the resilience of communities, and the character of an innovation ecosystems that shapes collaboration between traditional and modern science). **Two**, equally important, to advance any kind of TK protection by TK holders alone; as it will only be possible when indigenous and local communities are fully empowered to promote their TK, control TK uses by third parties and benefit from TK commercial exploitation.

In the following sections, particular focus will be dedicated to discuss these two barriers, and foreseen solutions currently contemplated by the international fora to overcome them, from the IP and beyond IP (Non–IP) perspectives.

### *2.4. Main options used by individual countries to protect traditional knowledge*

Several options have been used in time to protect various aspects of traditional knowledge in different countries. Main options used to legally protect TK can be summarised into two categories: Intellectual Property Options and Non–Intellectual Property Options, as follows:

IP SYSTEM OPTIONS:

For policy–makers when considering legislative options for the IP protection of TK, it is first necessary to examine the available legal and policy options under conventional IP systems. Existing IP rights can indeed be useful for the protection of traditional knowledge generally including cultural heritage, practices and knowledge systems of indigenous peoples and local communities (*lato sensu)* using for example rights granted by laws on trademarks and geographical indications, as well as the protection afforded by unfair competition laws, can be helpful in protecting reputations associated with TK and related goods and services [16]. If there are gaps in existing national legislation, it may be possible to fill them by adapting the existing IP framework.

Depending on protection needs and the existing IP framework, the options are:

- Use of existing IP measures and systems.
- Development of additional regulatory mechanisms.
- Adaptation of legal mechanisms unrelated to IP.
- Additions or amendments to existing legislation (filling in the gaps).
- Development of special (sui generis) laws and regulations.

NON–IP OPTIONS:

Appropriate legal mechanisms that are not related to IP can be adapted and supplemented to promote and enhance protection of TK. Such mechanisms include **legislation** on culture, on the intangible cultural heritage of folk arts and crafts, **on the conservation of biodiversity**, on farmers' rights, and on indigenous peoples and

local communities. The most used Non–IP Options, are also called *non–normative options*, include:

- Laws on unfair competition.
- Trade practices.
- Consumer protection and labelling.
- Use of contracts.
- Customary and indigenous laws and protocols.
- Civil liability.
- Unjust enrichment.
- Rights of privacy and blasphemy.
- Criminal law.
- Common law remedies.
- **Regulation of access to genetic resources and associated TK**.

Additionally, being the focus of this research traditional knowledge understood as **knowledge, know–how, skills, innovations** and practices associated to the management of genetic resources (*stricto sensu)*, in the cases where adapting existing IP rights may not be considered sufficient to cater for the holistic and unique character of TK decision may then be taken to protect through **sui generis systems** [16], which normally consists in specialized measures or laws aimed exclusively at addressing the characteristics of **specific subject matter** such as traditional knowledge associated to the management of genetic resources to preserve and maintain natural ecosystems (TK–GR). In such cases, it will also be necessary to take into account and coordinate with non–IP legislative and policy measures such as those concerning cultural diversity and cultural heritage, regional development, **the conservation of biodiversity**, the promotion of the use of traditional medicine and the **collection of ecological TK**. This is the focus of this research.

In the following sections, the emphasis will be on IP options available under conventional IP systems useful to protect TK in order to identify gaps existing in the various national legislation and possible efforts undertaken by the international community to fill them by adapting the existing IP framework. On a point of TK related to the conservation of biodiversity a section dedicated to TK protection through the **sui generis systems** offered by the Convention on Biological Diversity (CBD) will also be considered (under PART II) to show the defining characteristics of a largely agreed non–IP mechanism that coordinates with IP system to bring about measures to protect traditional knowledge (know how, skills, innovation and

practices) associated to the management of genetic resources (*stricto sensu)* in its various dimensions: cultural diversity and cultural heritage, regional development, **the conservation of biodiversity**, the promotion of the use of traditional medicine and the **collection of ecological TK**.

### *2.5. Legal and policy IP options available under conventional IP systems to protect TK associated to genetic resources*

Intellectual property (IP) is a legal discipline that has been around for decades to offer tremendous opportunities for researchers, scientists, creators and inventors to yield social and economic benefits from their intellectual–based creations [17]. As IP systems become more relevant with the spread of new technologies, such as biotechnology, there has been a concomitant interest by the international community in discerning the social, economic, and political implications of also protecting traditional knowledge associated to the management of genetic resources (TK–GR) to benefit indigenous peoples and local communities (IPLC) as guardians of natural ecosystems genetic resources around the world. As a response, a new–fangled link between IP & TK–GR is emerging to have ground–breaking implications for the future development of the IP systems on two interrelated levels: **first**, in determining to what extent the IP system can help increase the **socio–economic impact** that TK protection can have on TK holders, as traditional source of innovation prosperity, when engaged in preserving natural ecosystems biodiversity from degradation or extinction; and, **second**, in determining what kind of **governance** should be advanced by relevant international frameworks to make possible TK protection and its practical enforcement.

#### 2.5.1. To what extent the IP system can help increase the socio–economic impact of TK–GR protection via innovation prosperity?

In general, the IP system is designed to acquire and assert IP rights thereby preventing unwanted, unauthorized or inappropriate uses of IP rights by third parties (including culturally offensive or demeaning use) and/or to exploit their IP–based innovations commercially, for example through the granting of licenses, as a contribution to their economic development. Taking stock of how IP options are used to protect TK from *biopiracy*, it appears that there are kinds of protection that TK *lato sensu* can enjoy through conventional IP systems and institutions. However, among IP options are used to protect TK–GR, the **patent system** and the plant variety protection are the ones contemplating protection of **genetic resources** via TK subject matter.

Country experiences confirm that the use of conventional Patent System for TK–GR protection poses more limitations than direct compensations as it establishes that the exclusive right granted for an invention (product or a process) that provides a new way of doing something, or offers a new technical solution to a problem should fulfil conventional conditions to determine its novelty, inventive step, industrial application. For this reason, TK as such cannot be patented, since it does not satisfy the novelty and/or inventive step criteria. Besides, any invention which is made public before an application is filed would be considered prior art (although the definition of the term "prior art" is not unified at the international level, in many countries, it consists of any information which has been made available to the public anywhere in the world by written or oral disclosure. Thus, if TK is disclosed, a patent cannot be granted on an invention based on such knowledge. Nevertheless, according to the conventional Patent system, some TK–based inventions may meet the requirements of patentability if the details of the TK are not published or widely known (including to patent offices). Patentable inventions containing elements of TK may include, for example, previously unknown foods and their manufacturing methods; personal and household goods; devices and methods for farming, hunting and fishing; ways to prevent and/or treat diseases in humans or animals; and medicines derived from plants. Such inventions are generally covered by Section A, "Human necessities", of the International Patent Classification (IPC).

### 2.5.2. General issues that the IP system should still overcome to effectively help preventing biopiracy via TK protection

*The first issue* that TK finds in the effort to secure IP *protection* in the international arena refers to that embedded in the establishment of the World Intellectual Property Organization (in 1967), which Convention does not include TK in the list of types of intellectual property rights it provides for protection, despite the fact that TK is considered as innovation of indigenous peoples and local communities and product of creative intellectual activity and therefore "intellectual property". The Convention list includes creations of the human mind such as inventions, designs, literary and artistic works, performances, plant varieties, and names, signs and symbols.

*The second issue* is that there is as yet no accepted *definition* of "traditional knowledge" at the international level. The current working definition (offered by the WIPO) considers traditional knowledge (TK), as a broad description of subject matter, in *lato sensu* generally includes cultural heritage, practices and knowledge systems of indigenous peoples and local communities. It is considered a living body of knowledge that is developed, sustained and passed on from generation to

generation within a community, often forming part of its cultural identity. In *stricto sensu* is also understood as **knowledge, know–how, skills, innovations** and practices that are passed between generations in a traditional context, and that form part of the traditional lifestyle of indigenous peoples and local communities who act as their guardians or custodians. In this context, the term "traditional" does not mean "old" or "antique". Indeed, for the most part, traditional knowledge is neither ancient nor inert, but a vital, dynamic part of the lives of many communities' **frameworks of on–going innovation and creativity**.

*The third issue* refers to the fact that traditional forms of creativity and innovation under conventional IP systems are generally regarded as being in the *public domain*, and thus free for anyone to use. Yet indigenous peoples, local communities and many countries reject a "public domain" status of TK and argue that this opens them up to unwanted misappropriation and use. For most countries, this contentious association of TK with public domain, from the perspective of the conventional IP law, justify TK misappropriation. This is exacerbated by these communities' lack of experience with existing IP systems and, in many cases, lack of clear national policy concerning the utilization and protection of TK. In fact, often indigenous peoples and local communities tend not to make proper distinction between tangible and intangible assets which indirectly deprive them from income generating activities options and commercial competitiveness.

### 2.5.3. How is the International Framework responding to IP system issues to protect TK?

**The absence of TK from WIPO IPRs list**: to tackle this deficiency, in 2000, WIPO members established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and agreed to develop an international legal instrument (or instruments) that would give traditional knowledge, genetic resources and traditional cultural expressions (folklore) effective protection. Such an instrument could range from a recommendation to WIPO members to a formal treaty that would bind countries choosing to ratify it.

Since the IGC was established (22 years ago) the coordination with international and regional activities effort continues and discussions on the IP protection of TK and issues concerning IP aspects of the use of genetic resources mostly remain under consideration. Negotiations in the IGC towards the development of an international legal instrument for the effective protection TK to address the IP aspects of access to and benefit–sharing of genetic resources progress are progressing in favour of a sui

generis approach, i.e. in the effort to clarify the gaps in the existing framework of IP protection, the IGC is learning how a sui generis system is intended to fill these gaps from individual countries experiences that have sui generis systems in place.

Recent actions undertaken by WIPO–IGC in favour traditional knowledge [defensive] protection includes amendments recently made to the WIPO–administered Patent System to facilitate TK–related patent search when patent examiners use conventional patent search tools. These systems are: *the International Patent Classification (IPC)*, which has been expanded to take better account of TK subject matter, in particular concerning medicinal products based on plants extracts; and *the Patent Cooperation Treaty (PCT)*, also expanded to include eleven TK–related information resources, thus increasing the likelihood that relevant TK will be located at an early stage in the life of a patent.

**WIPO working TK definition now contemplates genetic resources preservation**: traditional knowledge *stricto sensu* definition sanctions the association of *traditional knowledge with genetic resources*, stating that traditional knowledge is a large body of traditional knowledge closely associated with the traditional management of genetic resources (GR) dedicated *among others* to preserve medicinal plants, traditional agricultural crops and animal breeds. It also states that TK often provides researchers with a lead to identify some molecules, properties or active ingredients within biological resources or provide information on how to use the GR and that genetic and biological resources are linked to TK and traditional practices through the utilization and conservation of the resources, which has occurred over generations, and through their common use in modern scientific research.

This working TK definition also denotes the potential economic value of GR and anticipates the significant implications for the IP system that the relationship between traditional knowledge (TK) and the use of genetic resources (GR) has due to the spread of new TK–based technologies, such as biotechnology, and their increasing share among patentable inventions [18]. Consequently, TK–GR holders began to argue that the *patent regime* should more proactively help to prevent TK biopiracy (misuse and misappropriation) through the promotion of fair benefit–sharing between holders of those assets (mostly biodiversity–rich countries) and those with the modern technologies to access and use them [19].

**The public domain issue is now tackle via sui generis systems:** under the conventional IP system, the issue of TK being regarded as in the *public domain* encompasses three evolving perspectives that are related but not necessarily consistent: (i) the legal status of biological and genetic TK related materials (TK as intellectual product) are

free from IP rights when the invention does not fulfil the conditions of patentability (novelty, inventive step, industrial application); (ii) the freedom to use biological and genetic TK related materials, makes TK free or available for any member of the public to use for any purpose without having to obtain the consent or permission of a right owner and without charge; and more recently (iii) in terms of availability and accessibility of biological and genetic TK related materials, contrary to some perceptions, they are not in the *public domain* simply because they are accessible or available through a free and *open source*.

On support of the later, some experts [20] argue that there is a fundamental distinction to make between being in the "public domain" and being "publicly available"; as the term *public domain* (used to indicate free availability of TK as intellectual product) has been taken out of context and applied to GR *publicly available*, in which case means that there is a condition to impose mutually agreed terms such as paying for access. Others [21] referring especially to biodiversity preservation, also claim that it cannot be assumed that TK associated with preservation and management of genetic resources that have been made available publicly do not belong to anyone. On the contrary, as elucidated by the Convention on Biological Diversity (CBD), the concept of *public availability* entails prior informed consent from a TK holder that is identifiable; and, by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the common understanding of *publicly available* does not mean available for free, but rather means that there is a condition to impose mutually agreed terms such as paying for access. The *public availability* concept will be retaken in PART II (within the context of Environmental Governance).

### *2.6. Patent system offerings and limitations to protect TK–GR*

The **patent system** offers to traditional knowledge associated to the management of genetic resources to preserve and maintain natural ecosystems (TK–GR) the following provisions and limitations:

- A legal system for TK protection where gaps are identified and negotiations to fill them can be structured.

- A Patent System eligibility criteria/requirements [novelty, inventive step, industrial application], that limits protection as it does not allow TK–GR validation under the context of conventional science–based approaches to the study of biodiversity, given that TK–GR cannot be patented as it does not satisfy the novelty and/or inventive step criteria (see point 18). This topic has been subject of debate and

controversies as, on the one hand, TK–GR novelty is questioned because it is generally made public before any possible patent application is filed by TK–holders. It would be considered prior art. Thus, once TK is disclosed, a patent cannot be granted on an invention based on such knowledge. On the other hand, some TK–based inventions may meet the requirements of patentability if the details of the TK are not published or widely known (including a patent incurring in biopiracy) provided that the patent office does not trace the TK involved. This has led the CBD to anticipate a solution to biopiracy, via Patent disclosure procedure, where TK–based innovations should disclose TK origin.

- Main efforts made to take the *"biopiracy"* issue to international level via WIPO–IGC include: coordinating international and regional activities to encourage negotiations towards the development of an international legal instrument for the effective protection TK to address the IP aspects of access to and benefit–sharing of genetic resources progress through a sui generis approach that is emerging from gathered from individual countries that have sui generis systems in place to fill these gaps encountered on how to proceed with the IP protection of TK and on issues concerning IP aspects of the use of genetic resources.

- Subsequent amendments made to the WIPO–administered [Patent] systems to facilitate TK–related patent search when using conventional patent search tools, include expansion of: *the International Patent Classification (IPC)* to take better account of **TK subject matter**, in particular concerning medicinal products based on plants extracts; and *the Patent Cooperation Treaty (PCT),* to include eleven TK–related information resources, thus increasing the likelihood that relevant TK will be located at an early stage in the life of a patent.

As an IP option, the offerings of the Patent System are currently under scrutiny and are called to support sui generis systems that also contemplate non–IP options relying on the Patent system, as the CBD mechanism that will be examined in the Section ahead dedicated to Non–IP options. Following are examined in detail the Patent System offerings and limitations currently under scrutiny in relation to the capacity of the existing patent laws and legal systems to help increase the **socio–economic impact** that TK–GR protection can have on TK holders' prosperity when engaged in preserving natural ecosystems biodiversity from degradation or extinction.

### 2.6.1. Patent laws and legal systems offer two approaches to protect TK holders' rights

Discussions about the forms of TK protection have arisen in policy debate two specific demands on the IP system: **the first**, call for the IP system recognition of the rights of TK holders relating to their TK within the positive protection so as to give TK holders the right to take action or seek remedies against certain forms of misuse of TK. **The second**, raises concerns about the unauthorized acquisition by third parties of IP rights over TK and asks for support to strengthen defensive protection that safeguards against misappropriation or illegitimate IP rights taken out by others over TK subject matter, since genetic resources (GR), as encountered in nature, cannot be directly protected as IP because they are not creations of the human mind. IP experts assisting the TK protection process have stressed that these two approaches should be undertaken in a complementary way because a comprehensive approach to protection in the interests of TK holders is unlikely to rely totally on one form or the other [22].

### 2.6.2. Positive Protection Approach works for TK under special circumstances

Under special circumstances, it gives TK holders the right to take action (for protection) or seek remedies against certain forms of misuse of TK using patents, trademarks, geographical indications, industrial designs, and trade secrets, although these laws would still require certain adaptations or modifications to make TK protection work better. On a point of encouraging positive protection of TK–GR by individual countries making use of the international patent system, it is pertinent to report the example of China that has been able to encourage Chinese practitioners to innovate within the traditional framework and use the **patent system** to protect their innovations with the robust Chinese State Intellectual Property Office team of patent examiners specializing in traditional Chinese medicine. As a result, only in 2001, China granted 3300 patents for innovations within the field of Traditional Chinese Medicine (TCM) [22]. This implies that these TCM patents were submitted as an international application under the *Patent Cooperation Treaty (PCT)* on the use of traditional Chinese medicine (CTM), which claims an invention that combines teaching of TCM with modern medicine. Similarly, systems have been developed to ensure that illegitimate patent rights are not granted over TK subject matter that is not a true invention (see "defensive protection" below).

### 2.6.3. Defensive Patent Protection Approach presents two options to protect TK–GR

**First possibility** aims at preventing illegitimate acquisition of patent rights by third parties over TK, although it does not stop others from actively using or exploiting TK. This is normally difficult to enforce due to lack of prior art information, accentuated by the lack of staff in the patent offices specialized in IP strategies for protecting *TK–based patents* [23]. In the effort to prevent erroneous patents granting, defensive protection relies on 'prior art', which presents two separate aspects to be addressed for TK protection: (i) legal aspects, to ensure that that information is published or documented in such a way as to meet the legal criteria to be counted as prior art in the jurisdiction concerned (this may include, for instance, ensuring that there is a clear date of publication, that the disclosure enables the reader to put the technology into effect, or to ensure that orally disclosed information must be taken into account); and (ii) practical aspects, to ensure that in fact the information is available to search authorities and patent examiners, and is readily accessible (such as through being indexed or classified), so that it is likely to be found in a search for relevant prior art. **Second possibility** aims at *disqualifying patent* applications that do not evidence compliance with Convention on Biological Diversity (CBD) obligations, i.e. with disclosure of origin (other than with related to fair and equitable benefit–sharing, that will be developed in detail in the next Section). On a point of encouraging positive protection of TK–GR by individual countries making use of the international patent system, it is pertinent to report the example of India initiative to amend the country's Patent Act in order to clarify the status of TK within patent law while embracing defensive protection approach.

## *2.7. Challenges that individual countries have found to mainstream TK–GR protection*

The modality of approaches used is mostly motivated by the growing commercial use of genetic resources beyond the traditional context (for example in biotechnologies), which individual countries can identify as a threat to local TK and has called for policymakers engaging in new policies and laws in this area. In light of this, the relationship between intellectual property (IP) and the protection, promotion, preservation and safeguarding of traditional knowledge associated with the management of genetic resources has given rise to a complex and on–going international debate. Broad policy debate underlines the general limitations of existing IP systems in meeting all the needs and expectations of TK holders; especially when conventional IP systems are used for "IP protection" and cannot stop

others from using or exploiting indigenous peoples and local communities' (IPLC) traditional knowledge. When it comes to TK–GR protection to prevent biopiracy committed at their expenses under the form of erroneous patents granted over inventions based on/or developed using TK–GR, practical country experiences suggest that TK–GR protection has no single template or comprehensive "one–size–fits–all" solution likely to suit all the national priorities and legal environments, let alone the needs of traditional communities in all countries, the international fora decided to work towards a coordinated "menu" of different options that provide for a comprehensive TK protection strategy that considers both specific IPLC's necessities and international standards for sustainable solutions while supported by the following key components:

(i) Policy initiatives, including political decisions to give greater attention and value to TK and their protection;

(ii) Legislative initiatives, including strengthening existing legal tools and creating new ones;

(iii) Infrastructure, especially inventories, databases and other information systems, which can complement and support the implementation of legal systems, and institutions, which can fulfil numerous functions; and

(iv) Practical tools, including the use of contracts, guidelines and protocols, as well as capacity–building and awareness–raising, if and when appropriate.

Country experiences also indicate that efforts to adopt and/or adapt conventional Patent systems via national and regional laws have only a limited impact because their protections only have legal effect in the country or countries in which they have been enacted and the only way to extend the conferred protection is by establishing bilateral or plurilateral agreements between countries that share a common interest in protecting traditional knowledge and have similar systems. As a result, they have started to share, both at national and regional level, a number of common objectives as a way to define what is to be protected and who is to benefit and how. These objectives often seek to:

(a) ensure that control over traditional knowledge rests with indigenous peoples or local communities;

(b) preserve and protect TK–GR against misappropriation and misuse by third parties; and

(c) promote equitable benefit sharing.

In support of promoting benefit sharing, is the claim that criticises policy debate about TK and the IP system for neglecting among the gaps and limitations to combat *biopiracy* that full adoption of TK–GR protection would only be possible when TK holders are fully empowered to promote their TK, control their uses by third parties and benefit from their commercial exploitation (as China and India are doing).

In the following Section particular focus will be given to the CBD mechanism as a non–IP option that relies on the Patent system to promote equitable benefit sharing.

## *2.8. Non–IP options and the link to IP sui generis systems useful for protecting TK and related biodiversity services*

For long at national level, the customary laws and cultural taboos of indigenous and local communities have long served to preserve their traditional knowledge and regulate its use [24]. Consequently, appropriate legal mechanisms that are not directly related to IP have been adapted and supplemented to promote and enhance protection of TK. Such mechanisms include legislation on culture, on the intangible cultural heritage of folk arts and crafts, on the conservation of biodiversity, on farmers' rights, and on indigenous peoples and local communities.

At international level, the representatives of TK holders have also expressed strong interest for the development of an international instrument that goes beyond the IP system in view of the growing commercial use of genetic resources beyond the traditional context (for example in biotechnologies). In light of this, the relationship between intellectual property (IP) and the protection, promotion, preservation and safeguarding of traditional knowledge associated with the management of genetic resources has given rise to a complex and on–going international debate, as it not only compromises **the socio–economic prosperity of TK holders' community,** but also the ways these communities can keep managing and preserving natural ecosystems' genetic resources.

In the effort to find a more comprehensive approach to TK–GR protection that satisfy the unique character of TK in the interplay of property rights, the practice of social norms, the operation of markets, the resilience of communities, and the character of an innovation ecosystems that shapes collaboration between traditional and modern science, the international community has identified a solution in the **Convention for Biological Diversity (CBD)** instrument that provides a compensation mechanism for TK holders when a TK–based patent is successfully granted and able to yield monetary and non–monetary benefits.

Since the CBD instrument is a sui generis Non–IP Options that relies on the Patent system to protect TK–GR, it is supported by the use of databases, patent examination guidelines, improved classification, search and examination tools, and contractual guidelines used to help patent examiners when assessing TK–based patent applications [25]. At country level significant work has been done by countries to facilitate their local TK visibility to patent examiners. India, for example, has compiled a searchable database of traditional medical knowledge that is habitually used by patent examiners as evidence of prior art (see point 46). Also at international level, relevant amendments have been made to the WIPO–administered systems, such as the expansion of *the International Patent Classification (IPC)* and *the Patent Cooperation Treaty (PCT),* to take better account of TK subject matter, increase the likelihood that relevant TK will be located at an early stage in the life of a patent, and facilitate TK–related patent search when using conventional patent search tools (see point 39).

In fact, main limitations of non–IP options that rely on the IP system, such as CBD to protect TK–GR, are due to inadequate monitoring and documentation of biocultural resources which has been a major challenge in most countries effort to promote local resources protection. The case of traditional knowledge is no different, with hardly sufficient systematic documentation of cultural practices in various biogeographic regions or sectors. In most local communities the knowledge is transferred in oral form and there is a rapid erosion of these knowledge practices. This raises a major concern to the challenge of preventing loss of biodiversity, erosion of traditional knowledge and that of preventing misappropriation of resources and associated TK. There are several other related issues such as assuring safety and quality of resources or knowledge, valuing resources and related knowledge, creating awareness and so on. Development of community biodiversity registers is considered a **sui–generis mechanism** under some national biodiversity legislations to protect traditional knowledge [10].

## 3. Part II: Environmental governance – Defining a global framework to support TK–GR protection

after looking at the literature that outlines the evolution of the IP policy debate in which the IP, TK and GRs relationship was recognised as having significant implications to avoid biodiversity loss by preserving indigenous peoples and local communities' (IPLC) role in a rapid evolving biotechnology innovation environment, it was conducive to assesses the **current environmental governance in relation to TK–GRs protection**

together with the challenges and opportunities that international institutional and political frameworks offer to support the most notorious non–IP options for TK–GR protection established by the Convention on Biological Diversity (CBD).

Findings indicate that the TK–GR protection mechanism offered by the CBD has all the potential to become an effective international instrument to regulate access to the world's genetic resources. The question of whether it is doable will be examined together with the practical recommendations still required for its full implementation across countries. For this, a practical example is offered to illustrate how indigenous peoples and local communities' skills can be embedded in technology transfer best practices to effectively adopt the CBD mechanism to produce new knowledge, innovation and prosperity from joint research and cooperation between traditional and modern scientists.

### *3.1. The Convention on Biological Diversity (CBD): a non–IP option for TK–GR protection that relies on the IP system for implementation*

The Convention on Biological Diversity (CBD) offers the most notorious non–IP options to **regulate of access to genetic resources and associated traditional knowledge**, while working in connection with **intellectual property rights** (IPRs); particularly **patents** but also **plant variety protection**.

Why the Convention on Biological Diversity (CBD)?

Because a large number of countries (196 participating governments) formally recognize that cross–border exchange of genetic resources and traditional knowledge should be carried out in compliance with the principles of the *Convention on Biological Diversity (CBD)*. With this in mind, the CBD was established (in 1992) **to reduce the global rate of biodiversity loss and to share the benefits from use of the world's genetic resources (GR)**. This CBD mission is echoed in its three main CBD objectives, as follows:

(1) Conservation of biological diversity;

(2) Sustainable use of the components of biological diversity; and

(3) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources (**ABS**), which can be monetary (i.e. royalties when world's genetic resources are used to create a commercial product) or non–monetary (including development of research skills and knowledge, *among others*).

Since the Convention recognizes that States have sovereign rights over their **natural resources** (GR) and have the authority to determine conditions for access to genetic resources in areas within their jurisdiction, it is vital that both users and providers of GR understand and respect institutional frameworks (such as those outlined in the Bonn Guidelines) and assists governments to establish their own national frameworks to ensure that access and benefit–sharing happens in a fair and equitable way in line with CBD principles contemplated in Article 15. In particular, the CBD (Article 15) outlines the following set of principles on access to and benefit sharing from the utilisation of genetic resources:

- Access to genetic resources must take place with the approval –or "prior informed consent" (PIC)– of the country from which the resource is accessed.

- Conditions for access to or use of genetic resources, including **how** any resulting benefits would be shared, must be agreed: access and benefit–sharing must be based on "mutually agreed terms" (MAT) to be negotiated with the country providing the resources (in some countries delegated to an agency or community). Furthermore, Article 8(j) of the CBD affirms the need for governments to "respect, preserve and maintain knowledge, innovations and practices of indigenous peoples and local communities". TO NOTE: this provision further calls for the approval and involvement of the holders and encourages the equitable sharing of benefits arising from the utilization of their knowledge, innovations and practices.

## THE **ABS** CONCEPT (A SUI GENERIS NON–IP OPTION) LINKED TO INTELLECTUAL PROPERTY RIGHTS (IPRs)

As mentioned earlier (point 53), the third objective of the Convention on Biological Diversity (CBD) is concerned with the fair and equitable sharing of the benefits arising from the utilization of genetic resources (ABS). The Access and benefit–sharing (ABS) refers to **the way** in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers). Hence, it provides **the way** to define what is to be protected and who is to benefit and how. Additionally, the access and benefit–sharing provisions of the Convention on Biological Diversity (CBD) are designed to ensure that the physical access to genetic resources is facilitated and that the benefits obtained from their use are shared equitably with the providers. In some cases, this also includes valuable traditional knowledge associated with genetic resources that comes from IPLC.

The benefits to be shared can be monetary, such as sharing royalties when the resources are used to create a commercial product, or non–monetary, such as the development of research skills and knowledge. It is vital that both users and providers understand and respect institutional frameworks such as those outlined by the CBD and in the Bonn Guidelines. These help governments to establish their own national frameworks which ensure that access and benefit–sharing happens in a fair and equitable way. Access and benefit–sharing is based on prior informed consent (PIC) being granted by a provider to a user and negotiations between both parties to develop mutually agreed terms (MAT) to ensure the fair and equitable sharing of genetic resources and associated benefits.

ABS is linked to provisions on access; **technology transfer and IP**; Strongly linked to the issue of "biopiracy", human rights, and the value(s) of genetic resources/ TK; International ABS regime (2010). For a number of reasons, **intellectual property rights** (IPRs), particularly **patents** but also **plant variety protection**, have become central to discussions on how to prevent **biodiversity loss** considering that:

- Biodiversity and associated traditional knowledge have tremendous economic potential;
- **Patent** claims in various countries may incorporate biological and genetic material including life forms within their scope;
- '**Patent** scope' is a feature of the patent system that enables corporations to misappropriate genetic resources and associated traditional knowledge or at least to unfairly free–ride on them;
- The ability of modern IP law to protect the innovations produced by industries is based mainly in/by the developed world and its inability to protect adequately those in which the developing countries are relatively well–endowed such as biodiversity; and
- The unequal distributions and concentrations of patent ownership and the unequal share of benefits obtained from industrial use of biogenetic resources are closely related.

## *3.2. How does ABS work with the Patent system?*

Growing recognition that there is a problem called *biopiracy* (or misappropriation) with regard to biodiversity and traditional knowledge, proposed solutions to address it include: a) **disclosure of origin**, and b) **certificates**. In this research the focus is disclosure of origin.

The Patent Disclosure Requirement (PDR) enables patent applicants to disclose any traditional knowledge used, or that are otherwise related to it, in the claimed invention. Existing patent law already requires some of this information to be disclosed by the applicant, but with patent disclosure requirements (PDR) the **focus on TK–GR is extended as a requirement within the patent disclosure obligations**. In principle, **PDR can be used as a tool** to help monitor the utilization of genetic resources and detecting when TK–GR based inventions eventually incur in "biopiracy" thereby affecting the human rights of TK–GR holders and the value(s) of genetic resources/ TK under the International ABS regime (2010). This is why ABS, legally regulated by Nagoya, is also considered a new, stand–alone sui generis IP systems which give rights in TK–GR as such.

### 3.2.1. Why is the CBD Patent Disclosure Requirement important in terms of TK protection but also of environmental governance?

The broad development underlying this new patent disclosure approach is that the reach of the intellectual property system in the global information society should extends to new stakeholders, such as indigenous peoples and local communities (IPLC), when their traditional knowledge constitutes an increasingly relevant body of 'prior art'. This is why, as mentioned earlier (see point 43), the effective identification of local TK in the world is of increasing importance for the functioning of the IP system.

### 3.2.2. The undergoing debate towards a globally accepted enforcement of the Patent Disclosure Requirement

The undergoing debate see, on the one hand, several countries already introducing PDR to serve the public policy goal of preventing the misappropriation of TK–GR that has been obtained without the authorization (e.g. without using prior informed consent, PIC) of the country thereby providing such resources and/or the indigenous and local communities holding such knowledge. On the other hand, those opposing, *mostly industry stakeholders*, showing no interest in developing new PDR in their own patent system although the Protocol is largely supported by the international community.

Large countries such as the US are not yet signatories of the Nagoya protocol (the legal binding instrument for ABS implementation, described in next paragraphs) and therefore do not embrace the PRD proposal. US officials [26] claim that main reason is that the US has already implemented some of the Nagoya principles.

For example, the **National Institutes of Health of the United States Department of Health and Human Services**, insists that before drug developers or researchers accept payment for biological and genetic material collected overseas, they must produce a statement declaring that they have permission (similar to PIC) to collect these materials from there and export them. Another reason mentioned, is the possible problems with the patent system, although the Justice Department's position on the patentability of isolated genes indicates a willingness to accept the Convention's broader goals, not only concerning genetics, but biological resources overall. It seems that the US will not pick up soon the Convention or the Nagoya Protocol as a priority item, especially given that it has remained dormant since 1994, although the stakes are high; in a 2009 report by Business Communications Company, the global market for botanical and plant–derived drugs predicted an increase from $19.5 billion in 2008 to $33 billion in 2013, a growth rate much more aggressive than that of the Protocol's signatories [26]. Other [27] argue that mandatory new PDR would reduce the legal certainty and predictability of the patent system, cause additional delays in the processing of patent applications and impede innovation.

In contrast, countries in favour of embracing PDR think that disclosure requirements can be designed to promote mutual supportiveness, synergies and complementarity between the implementation of CBD mechanisms and obligations while providing innovation incentives to the patent system [28]. It has been found, for example, that the implementation of new PDR at national level could strengthen the mutual supportiveness and complementarity between IP and ABS regimes under the CBD. For instance, PDRs have been used by some governments as tools for compliance with national (domestic) legislative, administrative or policy measures on access and benefit–sharing (ABS) that these nations have established.

## NAGOYA PROTOCOL (THE LEGAL INSTRUMENT TO IMPLEMENT THE ABS) ESTABLISHES A NEW GLOBAL ABS REGIME

In 2010 the **Convention on Biological Diversity** adopted a dedicated instrument, the *Nagoya Protocol* (NP), as **a supplementary agreement to the Convention** to provide a transparent legal framework for the effective implementation of the fair and equitable sharing of benefits arising out of the utilization of genetic resources (ABS), thereby defining what is to be protected (GR), who is to benefit (IPLC) and how (ABS). The objective of the Nagoya Protocol is **to set an international, legally binding framework to promote a transparent and effective implementation of the ABS concept at the regional, national and local level in the future**. In particular, the *Nagoya*:

- Provides a new and innovative definition of the utilization of **genetic resources** (GR) clarifying that 'utilization of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD".

- Makes the connection between genetic resources (GR) and **traditional knowledge** (TK) of indigenous peoples and local communities (IPLC) explicit. Article 8(j) of the Convention on Biological Diversity (CBD) which requires parties, subject to their national laws "to respect, preserve and maintain knowledge, innovations and practices of indigenous peoples and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity".

- Creates conditions of legal certainty and transparency for providers and users of GR and TK in the context of long–standing concerns by member countries about the problem of biopiracy or misappropriation of GR and associated TK in a legally and binding way.

- Establish that official check points now have to be designated in countries where GR has been utilised.

- Suggests that all ratifying parties (countries) need to translate the provisions of Nagoya into domestic laws or regulations (including those of the **Patent system**) that reflect the interest of all the stakeholders concerned (i.e. patent offices, Patent Libraries, Universities Tech–Transfer Offices, ministries of environment, NGOs, justice, health, business, local, etc).

### *3.3. Who is involved in the ABS regime implementation at the regional, national and local level?*

*Providers of genetic resources*: States have sovereign rights over natural resources under their jurisdiction and are obligated to put in place conditions that facilitate access to these resources for environmentally sound uses. Providers agree terms, which include PIC and MAT, for granting access and sharing benefits equitably. Laws within the provider country may entitle others, such as indigenous and local communities (ILCs), to also negotiate terms of access and benefit–sharing. The participation of ILCs is necessary in instances where traditional knowledge associated with genetic resources is being accessed.

*Users of genetic resources*: Users are responsible for sharing the benefits derived from genetic resources with the providers. They seek access to genetic resources for a wide range of purposes, from basic research to the development of new products. They are a diverse group, including botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries, collectors and research institutes.

*National Focal Points*: To facilitate access, users need a clear and transparent process that details who to contact and what the requirements and processes are in provider countries in order to gain access. National Focal Points are responsible for providing this information.

*Competent National Authorities* (CNAs): CNAs are bodies established by governments and are responsible for granting access to users of their genetic resources, and representing providers on a local or national level. National implementation measures establish how CNAs work in a given country

### *3.4. International bodies supporting ABS regime implementation*

In order to support the implementation and advance all regulations on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (**access and benefit sharing, ABS**), the Convention relies on an established institutional framework to assist with the conceptual and practical aspects. For the purpose of this research, three of the main bodies involved will be examined in relation to their role and approaches used to accompany Nagoya implementation. The main ones are WIPO and the FAO–ITPGRFA, as follows:

For the patent system and plant variety protection (via the International Union for the Protection of New Varieties of Plants, UPOV): the **World Intellectual Property Organization** Inter–Governmental Committee (WIPO–IGC) acts as an instrument which objective is to **support** the appropriate use and protection of traditional cultural expressions within the intellectual property. The WIPO Guide to Intellectual Property Issues in Access and Benefit–sharing Agreements is complementary and mutually supportive of the WIPO database of biodiversity–related access and benefit–sharing agreements, covers the conceptual and practical aspects of dealing with intellectual property in the context of access and benefit–sharing agreements. Its objective is to support providers and users of genetic resources and associated traditional knowledge when managing intellectual property issues in access and benefit–sharing agreements. It does so by explaining how intellectual property clauses may influence the approach and results of the utilization of genetic resources and

associated traditional knowledge, providing an overview of the types of intellectual property related issues that providers and users of genetic resources and associated traditional knowledge are likely to face when negotiating an agreement, and outlining the options available in managing those issues, thereby enhancing the information available to stakeholders.

For the pant variety protection (via FAO): the **International Treaty on Genetic Resources for Food and Agriculture** (ITPGRFA) of the United Nations Food and Agriculture Organization (FAO) is recognized as a specialized instrument under Article4 of the Nagoya Protocol. Specifically, the scope of the Treaty is limited to genetic resources for food and agriculture, as ITPGRFA is a global pool of some of the most important crop genetic resources for food and security which is shared and managed jointly by countries that adhere to it. The Treaty facilitates access and exchange of a specified list of crops through a multilateral system of access and benefit sharing thus further limiting the scope of the Treaty.

In the next section the institutional challenges that WIPO and FAO–ITPGRFA face to support ABS implementation will be examined in relation to the possibility of moving from a predominantly market–oriented self–regulatory approach (mostly supported by those opposing to PDR proposal) to an institutional approach of implementation (mostly embraced by those in favour and already adopting PDR in their Patent system).

### *3.5. What implementation approach for global ABS adoption?*

Main challenges that the WIPO and FAO–ITPGRFA face in advancing all regulations of ABS (under Nagoya Protocol) in a Multi–Level Governance Context lies in the fact that ABS **implementation** can lead to two fundamentally different processes: a market–oriented self–regulatory approach, which emphasizes the self–regulating capacity of the economic actors involved, or a normative institutionalist approach, which focuses on the norms and formal rules of institutions that not only support and frame, but also shape and constrain the actions of the players acting within them. This difficulty becomes evident when Nagoya intends to determine whether the protocol should be implemented on a voluntary or compulsory basis, which antagonizes with the approach adopted by sister agencies such as the International Union for the Protection of New Varieties of Plants (**UPOV**) to protect TK–GR. In particular due to the fact that the 1978 Act of the UPOV Convention allows members to apply the reciprocity principle; according to Article 3, any UPOV member "applying this Convention to a given genus or species shall be entitled to limit the benefit of the

protection to the nationals of those member States of the Union which apply this Convention to that genus or species and to natural and legal persons resident or having their registered office in any of those States". Without relevant provisions, this might open the door to negotiations between countries that decide to free ride the ABS regime.

On the one hand, developing countries experiences show that fragmented national and regional laws that protect TK–GR have only yielded limited impact and that the only way to extend the protection that the ABS Sui Generis protection system confers is by establishing bilateral or plurilateral agreements between countries that share a common interest in protecting traditional knowledge and have similar systems. This is significant, because the more TK–GR protection discussion elevates at international level, the more local TK holder communities tend to unwittingly lose control over it due to the challenging normative options they need to know, familiarise and manage to defend their entitlements for "IP protection".

On the other, objections to TK protection by large countries, such as US, are not necessarily motivated by bad faith, however they can affect IPLC's intellectual rights as they include the following three commonly expressed oppositions:

(1) When the public domain is threatened by every more IP protection systems one should not be creating new rights or extending existing ones to accelerate the inclusion of the public domain. This undergoing debate considers the following points of view: first, the position that not everything in the public domain should be in the public domain. To this, indigenous peoples' representatives contests that such assumption may inadvertently threaten their rights and argue that their biodiversity custodianship role and responsibilities do not necessarily cease to exist just because the knowledge has been placed in the so–called public domain. They also claim that a tremendous amount of TK has been disclosed and disseminated over the years without the authorisation of the holders. Second, there is a call for recognising existing IP rights, instead of creating new ones for TK protection. To this call, indigenous peoples' representatives agree with the condition that in the process of translating and codify existing rights in favour of TK protection in national courts and possibly across international borders is necessary to clarified what is public domain and what is not in relation to TK. Third, there is also the idea that TK holders should keep using their own regimes to regulate access and use of knowledge given that many traditional societies have their own custom–based "intellectual property" systems governing access to and use of TK. To this idea, indigenous peoples' representative recall that, even if one disregards customary law, the unauthorised dissemination or use

of certain publicly available TK could sometimes be challenged on the basis of concepts existing in the western legal system, such as copyright, breach of confidence and misappropriation.

(2) Biopiracy claims are exaggerated or even mythical, hence it does not represent a genuine threat to TK holders and their communities, therefore there is no need for a TK protection regime. To this unfounded perplexity, indigenous peoples' representative contends that "biopiracy" is used in various ways (see list above) and that there is evidence to elevate the debate beyond inaccurate information to achieve practical and effective solutions. Fortunately, countries such as Peru has undertaken opportune precautions and launched the most notable initiative to established a National Anti–Biopiracy Commission, which outcomes has been regularly reported to the World IP Organization Intergovernmental Committee (WIPO IGC) when discussing IP issues surrounding traditional knowledge, cultural expressions and genetic resources. This has made possible that in the event genetic resources are being accessed, used, "owned" and commercialised in ways that conflict with international law, the suspect should be able to accept that this is biopiracy too.

(3) If commercial users have to pay to access or use knowledge that has hitherto been freely available, they will simply not use it and no benefits will be generated to be shared with the TK holders and their communities. To this opposition to TK protection, indigenous peoples' representatives tend to refer to statistical evidence against such a view to proof that it is not at all credible and groundless.

### *3.6. Can ABS regime be implemented in the current context of Environmental Governance?*

The urgent need to implement Nagoya globally is reflected in recent declaration by UNEP [29] affirming that "Biodiversity loss and climate change, in combination with the unsustainable management of resources, are pushing natural spaces around the world, from forests to rivers to savannahs, to the breaking point," and warns "We absolutely need to protect, preserve and promote the traditional knowledge, customary sustainable use and expertise of indigenous communities if we want to halt the damage we're doing – and ultimately save ourselves.". The question here is: how to do it?

The European Union, as the main block signatory of Nagoya protocol, is dealing with the challenges that environmental governance poses. The European Union case

is considered as it can throw useful considerations for other countries engaged in this exercise. The EU has been taken necessary steps to close the implementation gap in the field of EU environment policy by first identifying the systemic reasons causing lack of good progress in implementation of environmental legislation and the way in which national, regional and local authorities manage the development of environmental policy, and compliance assurance. Specific issues affecting the effectiveness and efficiency of the European environmental governance, a recent assessment found [30], include how well resources (financial, biological and genetic TK related material, and human) are used in delivering environmental objectives, and whether there are effective mechanisms for ensuring that environmental issues are addressed in other areas of administration and policy. This makes transpire that the challenges for implementation of the Nagoya Protocol, as a typical "multi–level governance" case, is easier said than done.

In the attempt to understand these challenges, some authors [31] suggest that both "top–down" strategies (preparing environmental governance authorities to receive traditional knowledge) and "bottom–up" strategies (fostering the capacity of aboriginal people to bring traditional knowledge to bear in environmental decision making) have failed to overcome the significant barriers, among which communication. This, because communication arises from the different languages and styles of expression used by traditional knowledge holders; conceptual barriers, stemming from the organizations' difficulties in comprehending the values, practices, and context underlying traditional knowledge; and political barriers, resulting from an unwillingness to acknowledge traditional–knowledge messages that may conflict with the agendas of government or industry. Findings also sustain that the communication barrier combined with the recurrent co–opting of traditional knowledge by non–aboriginal researchers and their institutions, helps maintain a power imbalance between the practitioners of science and the current environmental governance and the aboriginal people and their traditional knowledge, as a result fostering the rejection of traditional knowledge or its transformation and assimilation into the Western–like IP systems [31].

### *3.7. How the rules for ABS regime implementation are dictated in the wider international negotiation scenario?*

Since the adoption of the CBD at the 1992 Earth Summit in Rio, the ABS implementation has become a major issue in international relations, as it has been seen by some as a way to redress the longstanding imbalances of the terms of North–South trade [32,33]. The inclusion of the concept of "fair and equitable benefit–sharing" as

the third objective of the CBD can be seen as the developing countries' responses to increasing trends of privatization of benefits, arising from genetic resources and the socialization of the costs related to their conservation and protection [34].

Moreover, the negotiations of the General Agreement on Tariffs and Trade (GATT), which pushed for the strengthening of intellectual property rights, led developing countries to replace their common–heritage strategy by (re)claiming sovereign rights over their genetic resources [35]. While dealt with under the auspices of an environmental treaty, the adoption of the Protocol is thus not just about the environment but also about international equity as a crucial component of any environmental regime, as explicitly recognized since the Stockholm declaration of 1972 [24, 36]. Never, since the negotiations of the Kyoto Protocol, has the subject of **equity** figured so prominently on the agenda of the international politics of the environment as during the tenth Conference of the Parties to the CBD, which led to the agreement of the Nagoya Protocol [37].

The importance of the issue is also reflected by the political priority given to the entry into force of the Nagoya Protocol (October 2014). Provider countries have increasingly ratifying (or acceding to) the Protocol, while user countries, in particular the European Union and its Member States, have started preparations for timely ratification. However, some authors [38] consider that the implementation of the Nagoya Protocol, as a typical "multi–level governance" case, entails dealing with the wide scope of subjects it addresses, and the multiplication of competent authorities and stakeholders handling these subjects at regional, national, and supranational level. This makes Nagoya implementation particularly challenging in terms of expected achievements. The authors then consider that **for an efficient governance system to be developed**, a permanent interaction between policymakers and governmental and non–governmental players will be necessary [38]. The implementation of the Protocol in a multi–level framework can however lead to two fundamentally different governance processes.

(1) **The first** type of implementation is based on a market–oriented self–regulatory approach to the implementation of access and benefit–sharing [20,39]. For some, the self–regulatory approach to ABS assumes that emphasizing the self–regulating capacity of the concerned economic plyers, either private or public and both for profit and not for profit, is the most effective mechanism to arrange access to genetic resources through ABS. The option in favour of market–oriented self–regulation does not mean that this mechanism cannot be subject to institutionalization and/or state support, but these means of support do not go beyond levelling the playing field between the actors involved in the

bilateral player–to–player contracting. Therefore, it is assumed here that the actors have fixed preferences and behave according to their expectations of how other actors will act.

(2) **The second** type of implementation process is based on a normative institutionalist approach of public action, which focuses on the norms and formal rules of institutions that not only support and frame the spontaneous interaction between agents with fixed preferences, but also shape and constrain the actions of the players and their preferences [19]. This approach other than being normative due to its formal or informal systems of rules is also prescriptive as it offers norms giving the actors a reason for action. The institutionalist approach assumes that it is both possible and desirable that the social and political institutions give the actors a reason to comply with, or be governed by, collective rules [22, 38].

In the current context of Nagoya implementation, **the market–oriented self–regulatory approach** seems to prevail by following the logic of the IP system, i.e. it takes the shape of market or quasi market driven implementation method through a governance of decentralized voluntary agreements [23, 28]. In this context, multi–level governance of ABS regime would mainly be concerned with improving the coordination needed for establishing player–to–player contractual agreements between stakeholders in both user and provider countries, such as information sharing and harmonization procedures [27, 28].

**The normative institutionalist approach** [for long expected by developing countries and the UNEP] would, instead, rely on the positive institutionalization of the core principles of the ABS regime within national legislation and public policies, beyond the minimal measures for the coordination of the bilateral contracting between economic actors [40]. While market–oriented self–regulation is, of course, likely to pursue general objectives of international equity and ecological sustainability, the normative institutional approach translates these fundamental normative principles of Nagoya directly into positive public norms. In doing so, this second approach, unlike the first one, allows the competent authorities to guarantee that the regulation of access, and benefit–sharing serves the environmental and social objectives of the Nagoya Protocol and the CBD. Such implementation therefore can include legislative action advanced via public policies. It is also likely to take the form of reflexive governance to direct the process of implementation while accompanying collective action that contributes to the goals of the Nagoya Protocol, in addition to "regulating social and individual action directly" [41, 42].

### *3.8. Learning from a national experience to quantify the socio–economic Impact from TK–GR protection*

Experiences from countries in Asia, Africa, Europe and the Americas, demonstrate how different communities' stakeholders are able to express their concerns and address them through co–engaged practice and learning in developing regionally appropriate solutions to the challenges of bio–cultural diversity. Such individual articulation and collective contextualisation demonstrate the biodiversity problematic (ranging from protection of species and ecosystems to poverty eradication, health and livelihood security), its relevance for the variety of stakeholders and an opportunity that WIPO IGC consultation, debate and learning spaces offers for mainstreaming issues of biodiversity into development agenda [10].

The Project of Potato Park of Cusco–Peru can be considered as one of the national cases that epitomises effective adoption of a comprehensive IP strategy for TK– GRs protection in the interests of biodiversity protection and the economic development of IPLC (TK holders). The project was adopted by the indigenous peoples and local communities in a coordinated "menu" of different options for protection as illustrated following.

#### 3.8.1. The Peru Potato Park Project goal

The main goals it is to develop biocultural heritage–based innovations for food security and climate resilience through "repatriation, restoration and monitoring of agro–biodiversity of native potatoes and associated community knowledge systems".

#### 3.8.2. The Project Key success factors

- The repatriation idea leveraged in the associated Quechua biocultural skills for practical use of new knowledge creation.
- Clear implementation standards: embracing ABS principles by the Quechua communities to facilitate positive collaboration with modern scientists to produce new knowledge and innovation from joint research.
- Clear strategic focus: determined by the leadership management and planning capability as well as the mission of the project's leading institutions, namely *Asociacion ANDES* and *The Potato Park* community–managed Biocultural Heritage Territory of Pisaq–Cusco, Peru.

– Meticulous process: distilled in the *Intercommunity Agreement for Equitable Benefit–Sharing*, which allows the community to determine for itself what equity consists of, and how to share benefits, which in turn enables the community to keep stewardship practices, i.e. an *expected 10% of the revenues of all the products and services that carry the Park's collective trademark to be channelled into a communal fund for its redistribution to the communities at the end of each year in accordance with the benefit–sharing agreement*.

– Inclusive governance*: for positive collaboration between indigenous* community groups and innovative institutions such as ANDES to share knowledge, group decision making and problem solving.

### 3.8.3. Measuring the ABS impact

It was anticipated that socio–economic impact from governing access to and benefit–sharing from the genetic resource's utilization is expected to be positive in terms of biodiversity protection and the economic development of IPLC (TK holders). This project has produced extensively qualitative and quantitative information so as to provide quantifiable evidence of the impact achieved since year 2000 (when the idea was launched). Achievements can be summarized as follows:

– The project has produced a positive impact at different scales in terms of new ways of making a living for local indigenous communities, alternative understandings of well–being, respectful relations between humans and nature, and alternative market values and relations.

– The breakthrough innovations created by this Project have been used to challenge the *status quo* of many local indigenous communities beyond Peru, designing and shaping alternatives to the current flawed global socio–political system in countries such as China, Panama, Kenya and India [32].

– Inclusive research methodologies bring justice and capacity into the foreground, i.e. they create capacity, and include the voices of marginalised indigenous farmers, particularly women, in processes which support the devolution of rights, empowerment, and the leveraging local collective knowledge and collaborative research.

– Many of the benefits identified reflect a transition within the current system, particularly in relation to adaptation in the face of climate change, which processes are essential to maintain the biocultural systems, which are the basis for

the future capacity of local indigenous communities to innovate to propose and implement alternative models of development and well–being.

### 3.8.4. Facts and Numbers

– In 2000 six Quechua communities from Pisaq, Cusco, Peru got fully involved and devoted to this project located in within the Cusco Valley, covers at total of 9,280 hectares and stretches from 3,400 to 4,900 metres (16,000 feet) above sea level.

– Some 410 native potato varieties were repatriated in the first year to the Park, bringing the Park's collection to a total of 1,344 different types of potato. This was done using repatriation agreement with various gene banks for the return of these varieties to their traditional communities and to prohibit the patenting of these varieties and related knowledge.

– Currently, up to 4000 potato varieties are growing in Peru in a high–altitude Sacred Valley of the Incas. For this reason the Park community organization is known as the "guardian of native potatoes".

### 3.8.5. Innovation Outcomes from joint collaboration between traditional and modern scientists

– The Potato Park itself is an innovation for inter–community role plaid in the TK–GR stewardship in collaboration with modern scientists.

– Governance is done by indigenous communities rather than governments and pushes indigenous communities towards an IP–based innovation economy.

– The technological innovations generated to halt biodiversity loss while increasing communities' income, include:

  • Improved preservation of native seeds; traditional forms of management of land and crops; forms of seed conservation, and forms of food preparation.

  • Increased capacity to manage biocultural protocols; forms of social intra–community control (agreements, association of communities, etc.), and ceremonies and festivals celebrations.

  • Strengthened capacity to commercialise community products in seed fairs and farm fairs.

- Better seed production infrastructure (seed producers).
- Local production diversification with production of associated goods (teas, creams, etc.).
- More off–farm activities, including touristic routes and craft products.

According to a former project director [32] "The landmark agreement between indigenous communities and the Potato Park for the repatriation and monitoring of native potatoes represents a fundamental shift in TK and GRs protection approach that rather than seeing farmers only collecting crops for survival, also obtain from scientists their gene bank in return to achieve agricultural prosperity. The disease–free seeds and scientific knowledge gained have boosted food security, and the new varieties have enhanced income, enabling the communities to develop novel food products." This has been confirmed by the fact that project has successfully evolved reflecting the inherent links within social–ecological systems, and between biological, cultural diversity, while also integrating new elements from outside knowledge, practices, and institutions. Links that are perfectly embody ABS principles.

## 4. Conclusions

In order to establish pathways to the future of TK protection, it is vital that such an effort is framed by a positive agenda. To do so, one should first ask: what is to be negotiated? In concluding this research, two sets of questions should be considered in future **international negotiations**: **First**, should first efforts be devoted to developing a national sui generis system (as in the case of Peru) in order to gain experience that makes it easier to determine what a workable international solution should look like **or**, as an alternative priority, is a multilateral settlement (such as the CBD–ABS–Nagoya) a pre–condition for the effective protection of the rights of TK holders in any country? **Second**, as a consequence of the first, how might concerned countries overcome the limitation within their own national sui generis systems to protect TK? Should efforts be devoted to developing an international sui generis system first in order to make it easier to determine what to adapt to a workable national solution should look like? In which case a multilateral settlement becomes a precondition for the effective protection of the rights of TK holders in any country? And what kind of a multilateral settlement may bring to an approach that is acceptable to all parties?

While each country will answer these questions differently, there seems to be consensus among countries to support sui generis systems of positive protection

(as it is the case of China, for example, see point 42) and groups representing TK holding people and communities that the problem with having a national system in a world where few such systems exist is that no matter how effective it may be at the domestic level, it would have no extra–territorial effect. Consequently, TK right holders would not be able to secure similar protection abroad, and exploitative behaviour in other countries would go on as before.

As a way out to this problem, there is the assumption that if a group of concerned countries decided to act strategically as a group, some interesting possibilities could emerge. Members of such a group could agree upon harmonised standards and then apply the reciprocity principle so that protection of TK would only be extended to nationals of other members (as it is the case of Peru, see point 85). Of course, the group should not be an exclusive club. Other interested countries should also be able to join subject to their enactment of similar legislation. As a new category of intellectual property, the members would just have to comply with the reciprocity principle and the preferential treatment afforded to nationals of group members would not have to be extended to non–group members who might then feel encouraged to sign up to the same standards and thereby enjoy the same treatment.

In light of that, concerned countries should not wait for final solutions emerging from WIPO–IGC now undergoing for 22 years with outcomes that tend to privilege the adoption of sui generis systems. In fact, the developed countries have created the main precedents in this direction. The United States, for example, in matter of Semiconductor Chip, successfully used the reciprocity principle by creating its own Protection Act to encourage other countries to enact similar legislation. The European Union is doing the same, for example on Legal Protection of Databases; with its 1996 Directive, to own the rights, database makers or right holders must be nationals or residents of an EU member state, or in the case of a company, it must have offices in a member state and be genuinely linked with the economy of a member. Non–qualifying makers, such as foreigners who produce their databases in another part of the world, will only acquire protection if there is an agreement between the European Union and the relevant country to extend protection to their nationals. The lesson to learn here by TK–GR concerned countries is that, it is likely to require that a group of countries (as suggested in point 95) to establish a similar system to allow group members to secure protection in return.

On a point of protecting genetic resources, sister agencies of the WIPO and the FAO–ITPGRFA, such as the International Union for the Protection of New Varieties of Plants (**UPOV**), introduce a dichotomy when choosing which an approach that best accommodate the desires of all members. Should the implementation be in

line with the **market–oriented self–regulatory approach** or rather in line with **the normative institutionalist approach?** (see point 84–86). In fact, the 1978 Act of the UPOV Convention explicitly allows members to apply the reciprocity principle (see point 78) which allows any UPOV member "applying this Convention to a given genus or species shall be entitled to limit the benefit of the protection to the nationals of those member States of the Union which apply this Convention to that genus or species and to natural and legal persons resident or having their registered office in any of those States.", which under the CBD regime instead would require to comply with PDR, and relevant Pic and MAT before any commercial activity is undertaken with the transfer of biological and genetic TK related material. These opposing approaches under the same umbrella have caused delays in implementation and tend to support the suggestion to concerned countries of not waiting for final solutions but to engage in sui generis systems that steer the process of implementation and support collective action that contributes to the goals of the Nagoya Protocol, in addition to "regulating social and individual action directly".

## 5. Practical recommendations to policy makers

the most important recommendation in the current scenarios is to act on the understanding that different countries have varied interests and concerns in respect of traditional knowledge and technologies. It is also to consider that sometimes their positions could be based on different assumptions and conceptual stances vis–à–vis traditional knowledge (TK). TK–based technologies and TK–holders. Others include:

- Consider that the urgency is to respond to the loss of biodiversity that may incur in further deterioration or even extinction if TK–GR protection do not find a workable solution.
- Ensure that national policies and multilateral–level negotiating positions and strategies are consistent, coherent and mutually supporting.
- Encourage the active participation of traditional knowledge and technology holders and traditional communities in both the formulation of national policies and of multilateral negotiating positions.
- Do not expect early solutions to this issue at international level. Devising workable measures and achieving consensus on their adoption will take a long time given the complexity of the issue, the stakes involved and the conflicting interests of the various stakeholders.

- Be aware that many otherwise sympathetic people oppose the creation of new property regimes on the grounds that they will shrink the public domain. Hence, it would be advisable to highlight during negotiations that a sui generis system based upon customary law would not contemplate the knowledge commons as it just intends to recognise property rights that already exist but which are not respected.
- Therefore, avoid or discourage protracted discussions on the applicability of existing IPRs to traditional knowledge, technologies and cultural works and expressions, and on the "need" to define traditional knowledge and technologies first before solutions may be formulated. Rather, enable the adoption of PDR via ABS regime as much as possible.
- Place the interests of indigenous peoples and traditional communities at the centre of all negotiating strategies on traditional knowledge, innovation and technology transfer.
- Take the opportunities arising from the fact that IP–TK–GR topics are now the subject of substantive proposals in various forums which have the broad support of many countries.
- Adopt a long–term vision is essential while expecting clear and realistic goals when it comes to TK. This can be formulated based on an informed calculation of what is necessary and feasible. A
- Consider that, although very slow, the IGC's discussions so far have been substantial and constructive. This means that some possibility exists for some Nagoya legally binding norms to be adopted, if enough developing countries can agree on what these norms should be and are willing to act together.
- As developing countries continue implementing intellectual property–related treaties at the multilateral, regional and bilateral level, appropriate communication and capacity building will be crucial if these countries are to effectively use intellectual property and other tools in pursuit of their sustainable development goals. For example, ensuring the effective participation of TK holders will be an important part of that challenge when exploring ways and means to protect and promote traditional innovation and creativity at the local, national and international level.
- Note that bilateral and regional free trade and investment agreements which in turn have proved to be a useful way for the United States (US) and the European Union (EU) to get individual, or sometimes groups of, developing countries seeking enhanced access to developed countries markets to introduce provisions

such as: (i) extending patents and copyright to new kinds of subject matter; (ii) eliminating or narrowing permitted exceptions including those still provided in US and European IP laws; and (iii) extending protection terms.

- Be aware that such bilateral and regional free trade and investment agreements make theoretically possible for developing country negotiators to bind the US and EU to measures that further their interests (as they seldom achieve any concessions at all in IP). Consequently, the risk exists that these and developed countries may use these trade agreements to get developing countries to abandon their demands concerning traditional knowledge and genetic resources in exchange for advantages in other areas of trade.

Finally, negotiations can positively evolve among developing and developed countries whenever necessary observations are taken into account. To illustrate this in practical terms, the example of a **Peru–US Trade Promotion Agreement** signed in 2006 is worth mentioning as it included a document called the "**Understanding** regarding biodiversity and traditional knowledge". The Understanding allowed "the Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development." [34]. In this Understanding, it is worth mentioning, the parties also recognise the significance of: (a) securing informed consent (equivalent to the PIC stipulated by ABS) from relevant country authority before accessing genetic resources under the control of such authority; (b) equitably sharing and benefits arising from the use of TK–GR; and (c) promoting quality and fair patent examination as to make ensure that the conditions of patentability are fulfilled. These are important concessions on the part of the US, as the Understanding states that "the Parties recognize that access to genetic resources or traditional knowledge, the same in terms of equitable sharing of benefits ultimately resulting from use of genetic resources or associated knowledge, which can be duly addressed through contracts that reflect mutually agreed terms (equivalent to the MAT stipulated by ABS) between users and providers." This lead to think that such contracts may be sufficient to meet the needs of genetic resource provider countries and TK holding communities. Not surprisingly, when asked about reasons why US is not taking part in the Convention on Biological Diversity (CBD) and therefore in the effort to halt biodiversity loss (see point 66), the US has consistently argued that the use of contracts makes it unnecessary to adopt new multilateral norms and reforms to the international IP regime aimed at regulating access and benefit sharing. Nevertheless, the lesson to learn here is that within the boundaries of this Understanding, at least there is nothing in it that prevents Peru from taking the measures it has already undertaken domestically and regionally and is proposing at the multilateral level.

## 6. Abbreviations

**ABS** – Access and Benefit Sharing
**BES** – Biodiversity and Ecosystems Services
**CBD** – Convention on Biological Diversity
**GR** – Genetic Resources
**HDI** – United Nations Human Development Index
**IGC** – Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
**IP** – Intellectual Property
**IPC** – International Patent Classification
**IPLC** – Indigenous Peoples and Local Communities
**IPR** – Intellectual Property Rights
**ITPGRFA** – International Treaty of Plants Genetic Resources for Food and Agriculture of the Food and Agriculture Organization (FAO)
**MAT** – Mutually Agreed Terms
**NP** – Nagoya Protocol
**PIC** – Prior Informed Consent
**PCT** – Patent Cooperation Treaty
**TK–GR** – traditional knowledge associated to the management of genetic resources
**TK** – Traditional Knowledge
**UPOV** – The International Union for the Protection of New Varieties of Plants
**WIPO**– World Intellectual Property Organization

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