Intellectual Property, Traditional Knowledge, and Bioprospecting: Searching for Efficient Balance of Rights

by

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Abstract

The dissertation comprises five chapters examining interrelated legal and economic aspects of the protection of Traditional Knowledge (TK). Chapter One describes the value that Traditional Medicinal Knowledge (TMK) has and the alarming rate of loss it faces. The chapter outlines the various issues of contention from defining ‘traditional knowledge,’ to the argument surrounding if and how TK should be protected. Chapter Two examines economic rationales for the need to protect TK through the lens of the public goods literature. It outlines the three key causes of TK loss and alternative methods of producing TK. Building on such discussion, Chapter Three develops the ‘incentive to codify’ argument which forms a core part of the thesis, as distinguished from the currently dominant ‘incentive to conserve’ rationale. The chapter discusses existing piecemeal attempts to codify TK and posits that a proactive use of such database will enable these initiatives to realize their real potential. Chapter four outlines the legal framework which may be justified given the public goods nature of TMK and the need to codify and disclose it to users. It advocates for the establishment of a bioprospecting right which can reflect the interest of TK holders and users. It also outlines what form TK codification should take. Lastly, Chapter Five examines whether an international TK protection mechanism is necessary. It outlines existing international deliberations on TK protection including the Draft Articles of the World Intellectual
Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC). The chapter concludes with analysis of the key features that an international forum should consider to provide baseline protection.
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Aman Gebru
November 2016
DEDICATION

To my parents:
Abrehet Hailemichael and Kidanemariam Gebru
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Executive Summary

The dissertation examines legal and economic rationales for TK protection. It also investigates what framework is justified based on such rationales. It concludes that because of the public good nature of TK, the disincentive that knowledge holder communities have to codify and disclose their TK is a key feature that requires legal intervention. Legal intervention is intended to provide the necessary incentives to save TK from the alarming rate of loss it is faced with by codifying and disclosing it to the outside world. The dissertation focuses particularly on traditional medicinal knowledge (TMK) while some of the concepts discussed also apply to other areas of TK. Based on this justification the dissertation proposes the adoption of a legal framework that grants ‘bioprospecting rights’ – a cluster of rights granted to TK holder communities and emanating from bioprospecting activities by users. The dissertation also argues that baseline TK protection should be provided at the international level to realize the full potential of the bioprospecting rights framework. A more detailed description of the subjects discussed in each chapter is provided below.

CHAPTER ONE: TRADITIONAL KNOWLEDGE, BIODIVERSITY AND RATIONALES FOR LEGAL PROTECTION

This chapter outlines the many contentious features of TK protection discussions. The debate begins with what the definition or scope of the term ‘traditional knowledge’ should be. Different definitions have been provided, and narrow and broad definitions are analyzed. The narrow definition adopted in this dissertation defines TK as the know-how, skills, practices, innovations and learnings of indigenous people and local communities. The focus of the thesis is on traditional medicinal knowledge (TMK). However, since some of the discussion both in the literature and in different forums look at the whole of TK, references to TK are made whenever appropriate.

The chapter discusses the lack of TK protection under conventional IP laws. In general terms, existing IP laws have a framework that does not fit well with the needs and expectations of
knowledge holding communities. Furthermore, TK fails to meet the core requirements of patent laws such as novelty (newness) and inventive step (non-obviousness). The chapter also examines the close relationship of knowledge holder communities with biodiversity. Because such communities rely on biodiversity heavily, the destruction of biodiversity resources has had a devastating impact on TK as well. As a result, international instruments whose main focus is biodiversity conservation have also addressed TK issues, albeit on a more general level. Two modes of protection are identified in this chapter: defensive and positive protection. The dissertation focuses on positive protection of TK which seeks to provide knowledge holding communities with the power to control how their knowledge is used by outsiders.

Scholars have given differing justifications for the need to protect TK. These justifications have been clustered into those based on equity, distributive justice, human rights, property rights and consequentialist theories. The limited role that economic analysis has played in TK protection discussions has been identified as a problem that this dissertation seeks to address. Furthermore, all of these theories have a strong and weak aspect to them. The core limitation of most of the arguments discussed is their inability to bring key stakeholders from the user side into attempts to establish a protection mechanism. Arguments based on consequentialist concepts may generally have the potential to convince users such as biopharmaceutical firms and developing country governments to buy into proposed frameworks. While a consequentialist justification of the ‘incentive to codify’ is focused on in this dissertation, it does not seek to disregard normative arguments put forward by other scholars. The ‘incentive to codify’ argument is conceived as a supplementary argument to those based on equity, distributive justice, human rights and property rights, in so far as such theories could work with the framework detailed in succeeding chapters.

CHAPTER TWO: TRADITIONAL KNOWLEDGE AS A PUBLIC GOOD

In this chapter, TK is situated with other knowledge goods within the framework of non-rivalrous and non-excludable public goods. The various features of TK that place it in certain groupings based on various categorizations is discussed. In general terms TK is an uncodified, skill-embodied, higher-order impure public good. The purpose of categorizing TK in such way is to help in formulating policy judgments that reflect and respond to its unique feature. Consequently,
the key public policy features to focus on generally in the attempt to protect TK are: the fact that there is need for an urgent solution to address the alarming rate of TK loss; the need for continued collaboration between knowledge providers and users in order to transfer know-how and to sustain the production of TK; and the need to strike the right balance between knowledge providers and users.

The chapter explains the key causes for the alarming rate of TK loss: it's dominantly oral nature; the protectionist trend that has been adopted by source communities and countries in response the lack of protection; and the destruction of knowledge holder communities. The chapter concludes by considering alternative modes of producing TK such as secrecy, government provision, and group cooperation, among others. While these alternatives may support TK production, a market-based approach is also important given the urgency of the situation and the potential of the market to address the issue.

CHAPTER THREE: THE ‘INCENTIVE TO CODIFY’

Basing on such categorization of TK as a public good, chapter three outlines the ‘incentive to codify’ theory. It calls for a shift in paradigm from focusing on the currently dominant cultural conservation rationale to the utilitarian rationale. The gist of the argument is that there is an urgent need to encourage TK codification to save it from an alarming rate of loss. However, communities have a disincentive to codify their knowledge because codification will increase the public good nature of their TK by reducing the cost of access for outsiders. Thus, the incentive that knowledge holder communities need is to codify their predominantly orally-transmitted knowledge and not to conserve their culture as is widely claimed. The chapter makes analogy to the implication of patent laws for the codification of knowledge, to support the claim that legal intervention will encourage TK codification.

The chapter then discusses the needs and expectations of users and knowledge providers in a codification process. It concludes by outlining the various national and international attempts that have been engaged in piecemeal attempt to codify TK. While most of these attempts are currently used in a defensive mode to invalidate non-inventive TK-based patent rights, the real potential of
these codifications is in their proactive (positive) use. The succeeding chapters build on this need for positive protection that encourages proactive use of codified TK.

CHAPTER FOUR: A MODEL FRAMEWORK OF PROTECTION:

This chapter applies the public goods analysis of information goods provided in the previous chapter to the regulation of the use of TMK in bioprospecting. TMK is an information good and therefore its regulation has static and dynamic efficiency implications. Although providing exclusive rights over TMK may result in static inefficiency, this move could be justified if there are significant dynamic efficiency gains that result from the codification of this fast disappearing body of knowledge. Exclusive rights for the encouragement of the disclosure of TMK would promote dynamic efficiency gains.

There are vigorous arguments over what rule to apply for the protection of TMK. The major debate has been between granting a right protected under a property rule versus one protected under a liability rule. This chapter analyzes this debate and compares the two rules based on three core features: their effects on innovation; their ability to encourage the documentation and disclosure of TMK; and their ability to set price. Property rules seem to have better qualities for the regulation of TMK use in bioprospecting initiatives given their superior capacity to encourage TK codification and in setting prices. However, the difference between property rules and liability rules should not be overstated. Policy makers should consider adopting a mixture of these two rules in crafting an appropriate regime to regulate the bioprospecting industry.

This chapter outlines the need to establish two TMK databases: a publicly accessible database and a restricted database to which only the relevant government agency has access. It proposes the adoption of ‘bioprospecting rights’ – a cluster of rights which grant TK holder communities rights to conduct bioprospecting, share benefits from bioprospecting or receive compensation for unauthorized access to restricted TMK database. The rights has four core requirement: 1) that applicants have to be knowledge holding communities or their licensees; 2) if applicants are licensees, that they enter into the license through the Prior Informed Consent of knowledge holding communities and that there be a fair and equitable benefit sharing agreement; 3) that the
The chapter begins by examining the need for a multilateral protection regime. It shows that there are mechanisms such as secrecy and deferred disclosure that could be used to reduce the concerns related with territoriality of bioprospecting rights. However, it also acknowledges that the full potential of the framework would not be realized without an international mechanism of TK protection.

The chapter proceeds to examine the status quo in terms of relevant international instruments that might have implications for TK protection. It also examines the most advanced of such attempts – the Draft Articles deliberation in the World Intellectual Property Organization (WIPO). Although international TK protection has been discussed for over a decade, a clear and enforceable regime of protection has yet to be achieved. International deliberations at the WIPO IGC are stalled because of key issues on which countries have not been able to reach a consensus. These issues include the definition/scope of TK, the legal nature of proposed instrument, the tension between providing flexibilities for domestic policy space and crafting an effective/enforceable system of protection, and the relationship between the proposed instrument and other international agreements. The feasible way forward for international TK protection seems to lie in striking the right balance between providing flexibilities for domestic jurisdictions to craft domestic legislation based on the country’s needs and capabilities, and ensuring that there is a sufficient international obligation to establish a legal framework. Such a framework should begin from the minimum international consensus among key stakeholders in the global bioprospecting field.

In order to guide the development of such a minimum consensus and to strike a balance between flexibility and enforceability, it is proposed that the Draft Articles include five provisions on the
following issues: A provision defining TK and the general subject matter that should be subject to protection (currently included in Article 1 of the Draft Articles); A new article requiring the establishment of domestic frameworks that would encourage the codification and disclosure of TK through databases/registries; an article setting out enforcement measures (currently Article 4); provisions on national treatment and MFN treatment (currently Article 11); and a provision on the relationship of the instrument to other international agreements (currently Article 10). The international instrument should be limited to these few provisions and leave the details of the system for domestic legislation.

The requirement that patent applicants disclose the origins of TK used in the process of invention has been gaining momentum in the international TK protection deliberations. Additionally, the recognition of national legislation under international agreements has been proposed by scholars. These two substantive mechanism seems to have a potential to establish an effective international protection if the relevant international agreements such as TRIPs are amended to include them. The basic principles of national treatment and Most Favored Nation treatment borrowed from international IP law are also needed in order to supplement minimum substantive protection. Although FTAs are not the ideal tool to establish global norms, given that they are proliferating countries advocating for TK protection should begin to use them strategically to establish global norms of TK protection. In all of these efforts, it is suggested that the need to encourage the codification and disclosure of TK should be the organizing principles. Since this need has been endorsed in many instruments including the Draft Articles, it should be feasible to develop a global norm around such principles.
CHAPTER ONE: TRADITIONAL KNOWLEDGE, BIODIVERSITY, AND RATIONALES FOR LEGAL PROTECTION

1 Introduction

Society has long enjoyed the benefits of medical advances, especially medicines. In numerous cases, the biopharmaceutical industry builds on knowledge accumulated by traditional communities over the centuries. Recognition is usually given to the person or firm that produces a medical product or service at the end of the process of discovery. Information about the knowledge that allowed these medical advancements to develop rarely comes to the fore. This dissertation deals with ‘traditional knowledge’ and engages with questions of if and how the relationship between those who hold this knowledge and those who are using it should be regulated. This chapter begins with a description of the Hoodia story, an example that is intended to facilitate discussions of traditional knowledge and drug discovery throughout this thesis.

1.1 The Story of Hoodia or “Ghaap”

The San people and the Hoodia Plant

The San people are various hunter-gatherer communities that live in seven countries in South Africa (Botswana, Namibia, Zambia, Zimbabwe, Angola, Lesotho and South Africa). A considerable number of the San people live in the harsh environment of the Kalahari Desert, and as a result, are skillful in using resources around them to survive. Until the late 19th century, the San culture and knowledge was transferred orally and through rock paintings. During the early years of the colonial era, the San way of life changed significantly as a result of contact with settlers. Settlers hired the San to work on farms, and there were intermarriages between members

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1 This section is adapted from a chapter on the Hoodia plant in a book by Abena Dove Osseo-Asare, a historian at the University of Texas at Austin. The book provides a historical and anthropological background to the use of the Hoodia plant in suppressing appetite. See Chapter 5 – Take Kalahari Hoodia for Hunger, Abena Dove Agyepona Osseo-Asare, Bitter Roots: The Search for Healing Plants in Africa (London: The University of Chicago Press, 2014) at 165.
of different communities. Some San communities, however, moved further inland and into the Kalahari Desert to avoid contact with settler communities.

The Hoodia plant, also known as Ghaap in the local languages, is a succulent cactus-like plant that local community members chew on to suppress their appetite when they go on hunting trips. Although current discussions emphasize the use of Hoodia by the San communities, early reports refer to its use by other neighboring communities such as the Khoi (Bushmen) and Afrikaaners. As a result, it is unclear whether it is the San people or other communities in the Kalahari Desert who first discovered the use of Hoodia to suppress appetite. The first writings on the Hoodia plant date as far back as the 1700s. European explorers labeled the plant ‘Hoodia’ after a person named Mr. Hood in 1830. One type of Hoodia that later received attention from researchers was called ‘Hoodia Gordonii’ after Colonel R. J. Gordon, who either made/commissioned a drawing of the plant in the late 1770s.

*The Hoodia Plant and P57*

Since the early days of the colonial era, many institutions studied the way of life of the San people and other communities who lived in the Kalahari Desert. Institutions that conducted major studies include Harvard University, the Smithsonian Institute, the U.S. National Institute of Health, various organs of the South African government, and the University of Witwatersrand. Some of these studies examined the San people’s use of medicinal plants and food consumption. In numerous research projects, the San and neighboring communities described their use of hundreds of plants that have nutritional and medicinal qualities.

The Center for Scientific and Industrial Research (CSIR), an entity of the South African Government established in 1945, is a key institution which was involved in the study of the San people and other communities in and around the Kalahari Desert. One of the key objectives of CSIR was to increase the productivity of local community members who worked on farms by “improving” their nutritional intake. Hoodia had little potential to help increase the weight of the malnourished members of local communities such as the San, which led to the rejection of research into Hoodia in the 1960s. However, by the early 1980s rising obesity among settler
communities created a significant interest in losing weight. CSIR’s research direction changed from supporting local communities to gain weight to helping settler communities to lose weight. At the same time, CSIR received advanced research tools used in the extraction of active compounds from plants. These factors led CSIR to restart its research into the Hoodia plant.

Since CSIR is the key research institute in South Africa on nutrition and health related research, many entities, and individuals provided samples to the centre. Although there is no clear evidence that the San people or other communities provided samples directly to CSIR, Harvard University, among others, gave plants collected from their study of the San people to the centre. CSIR conducted research into Hoodia plants, which had shown anorectic effects in other research projects. After several years of research, CSIR scientists were able to identify and extract the active ingredient responsible for suppressing appetite. The names of the community informants who may have been involved in the research project were absent from the research reports, and internal communication related to the Hoodia research within CSIR remains inaccessible to the public.

Following the successful isolation of the active compound in Hoodia, CSIR entered into a collaboration with Phytopharm, a UK-based pharmaceutical firm with a focus on natural products, for the commercialization of P57. On year later in 1997, CSIR was granted its first patent in South Africa on the appetite suppressant qualities of the active elements extracted from the Hoodia plant, a compound the centre labelled P57. Phytopharm financed the international patenting of P57 and facilitated the licensing of the patent to Pfizer and Unilever. After signing a licensing agreement with Pfizer, Phytopharm made a payment of half a million dollars to CSIR. Unilever invested close to £20 million for the research and development of a weight loss product from the Hoodia extract.

**Benefit sharing from Hoodia**

When news of the patenting of an extract from the Hoodia plant reached the public, activists, academics, and non-governmental organisations began advocating, on behalf of the San people, for the sharing of profits related to P57. The Hoodia story unfolded at a time of a political shift
that prioritized wealth redistribution and affirmative action to previously oppressed communities in South Africa. The role of the San people and other local communities in the development of the P57 was only recognised post-Apartheid when minorities in South Africa started taking leadership roles in government institutions (including at CSIR).

Despite Phythopharm’s initial statement that there is no legitimate claim for a share of the profits because the San people are extinct, advocates later identified close to 100,000 members of the San community. The South African San Council and the Working Group of Indigenous Minorities in South Africa (WIMSA) established a jointly managed trust. The Council brought legal action against CSIR. In a settlement agreement, CSIR agreed to pay 6% of the royalty payments from P57 into the Trust. In May 2005, CSIR paid R560,000 South African Rand into the trust, which was planned to be spent on education and other projects that would create jobs for members of the San people. Following the settlement, members of San communities in neighbouring Botswana and Namibia claimed that they also deserved a share of the profit from CSIR. The Center found that managing claims from numerous local communities was inefficient, and at least one CSIR scientist called for the government to use its offices at different levels to manage the benefit sharing process.

While the San were hoping to share profits from P57, the marketing process hit a roadblock. Producing a marketable product from the Hoodia extract proved much more challenging than anticipated. Pfizer terminated its license in 2003 because of the challenges and high cost associated with synthesising and extracting P57. In 2008, Unilever ended its license because of adverse side effects of the compound. Meanwhile, other firms and individuals started producing dietary supplements without entering into a licensing agreement with CSIR or Phytopharm. After facing significant financial challenges and failing to enter into licenses with other major firms, Phytopharm stopped its development of Hoodia in 2010. CSIR continues to conduct research on the Hoodia plant with the agreement that Phytopharm will share in the profits of any future products from P57. Despite the inability of firms to create a successful pharmaceutical product, Hoodia-based products have become ubiquitous in the dietary supplement market.

*Post-Script (Epilogue)*
The South African government has enacted legislation regulating bioprospecting processes in part as a reaction to experiences such as the use of the extract from the Hoodia plant. The Biodiversity Act of 2004, and the Patent Amendment Act of 2005 is worth mentioning in this regard. The purpose of the legislations is to form a licensing system that would regulate the use of genetic resources and traditional knowledge for drug discovery. However, commentators have criticised the reforms as an over-regulation, claiming that the laws increased the burden of getting a bioprospecting license by requiring, among other things, that bioprospectors get a license for past acts of bioprospecting.

As for the San people, their story of collaborating in bioprospecting does not stop with the Hoodia plant. The San Council has recently entered into a benefit-sharing agreement with HGH Pharmaceuticals (a South African company) over *Sceletium tortuosum* or what is being called the “San Prozac.” The extract comes from a plant locally known as Kanna or Kagoued, which is traditionally used as an antidepressant. HGH Pharmaceuticals has been researching the plant and has developed a product called Zembrin, which has passed some of the regulatory hurdles in South Africa.

1.2 Defining Traditional Knowledge

The debate surrounding traditional knowledge (TK) protection begins in defining the term. Scholars have not yet come up with a universally accepted definition of TK. However, like many other concepts, there is sizable literature on its value, protection, and conservation. A number of conceptual and practical reasons make it hard to define TK, as discussed below.

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It must be noted at the outset that the term ‘traditional’ is not used to connote its antiquity.\(^3\) It does, rather, refer to the way the knowledge is developed, used and shared.\(^4\) While ‘modern’ knowledge uses evidence-based investigation, TK is characterised by trial-and-error methodologies and intuition.\(^5\) The value of the adjective ‘traditional’ will become apparent in succeeding discussions on the differences between Western and traditional knowledge systems.

1.2.1 What is ‘traditional knowledge’?

The variety of subjects it can refer to presents just one difficulty in defining TK. We can group the proposed definitions into broad (\textit{lato sensu}) and narrow (\textit{stricto sensu}) categories. According to the World Intellectual Property Organization (WIPO), TK in the broad sense refers to “intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities…”\(^6\) In this definition, TK is not limited to the content of the knowledge itself but includes the various associated practices, tools, symbols and expressions that come with it.\(^7\) Chidi Oguamanam also adopts a similarly broader – although slightly different definition.\(^8\) He embraces Howard Mann’s definition of ‘indigenous knowledge’ as that which includes “information, understanding, and knowledge that reflects symbiotic relationships between individuals, communities, generations, the physical environment,


\(^5\) Carvalho, supra note 3 at 244 (listing the four elements of TK including the fact that it based on “trial-and-error” approach). ; Jerome H Reichman & Tracy Lewis, “Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge” in Keith E Maskus & Jerome H Reichman, eds, \textit{Int Public Goods Transf Technol Glob Intellect Prop Regime} (Cambridge University Press, 2005) at 356.


\(^7\) \textit{Ibid}, Annex, Para 2.

and other living creatures, and the spiritual relationships of a people.”

The goal of broadly defining TK is to avoid fragmenting the holistic nature of TK and to recognise the traditional notion of interconnectedness. Stephen Brush, on the other hand, defines indigenous knowledge as “the systematic information that remains in the informal sector, usually unwritten and preserved in oral tradition rather than texts…[It] is culture specific, whereas formal knowledge is decultured.” Here, both definitions – that of Brush and that adopted by Oguamanam/Mann seem to have ignored the difference between ‘information’ and ‘knowledge’ and use the two terms interchangeably. As rightly noted by John Mugabe, knowledge requires practical skills and experience while information does not.

However, WIPO’s committee assigned to address the protection of TK — the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) — has adopted a narrower definition. It defines TK as the “content or substance of knowledge resulting from intellectual activity in a traditional context, [including] the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations.” Here TK is differentiated from the associated practices and expressions that the IGC refers to as Traditional Cultural Expressions (TCE). TCE include cultural expressions such as music, dances, paintings, sculptures, stories. However, the committee itself acknowledges that differentiating TK from TCE is not an easy task as they are intertwined with each other. For example, in some documents, the WIPO uses

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11 Ibid.
12 Ibid.
13 WIPO - IGC, supra note 6, Annex, Para 3.
traditional knowledge in a loose sense to refer to “… tradition-based literary, artistic or scientific works …”\textsuperscript{15}

For several reasons, this dissertation adopts the narrower version of the term provided by the IGC. First, the IGC definition makes the discussion of TK manageable in undertaking a detailed and coherent analysis. Second, the narrow definition is the one most frequently used in discussions found in the literature. Third, the economic analysis approach adopted in this dissertation lends itself more easily to know-how rather than artistic and literary knowledge, which tend to be dominated by aesthetic value. This is not to say that artistic and literary knowledge and expressions do not have economic value. To the contrary, such forms of expression and knowledge may hold an enormous amount of value in an economic sense. However, such value is also usually intertwined with aesthetic and artistic value. Therefore, TK here refers to the know-how, skills, practices, innovations and learnings of indigenous peoples and local communities. This is similar to the definition adopted by the WIPO-IGC, especially under the ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’.\textsuperscript{16} In other words, it refers to the content and substance of TK rather than to the cultural expressions associated with it. Yet, the fluidity of the concept of TK must, in general, be fully appreciated when attempting to implement the various rules and concepts related to it.\textsuperscript{17}

\textsuperscript{15} WIPO - IGC, \textit{supra} note 2, para 24.
\textsuperscript{17} Oguamanam, \textit{supra} note 8 at 20.
1.2.2 Who are the holders of ‘traditional knowledge’?

The second difficulty in defining TK arises from the task of identifying its holders. A variety of adjectives are frequently appended to ‘knowledge’ in this context, including ‘indigenous knowledge,’ ‘traditional knowledge,’ ‘native/aboriginal knowledge,’ ‘local knowledge’ and ‘informal knowledge.’\(^{18}\) Adopting the term ‘indigenous knowledge’, Stephen Munzer and Kal Raustiala define TK as “… the understanding or skill possessed by indigenous peoples pertaining to their culture and folklore, their technologies, and their use of native plants for medicinal purposes.”\(^{19}\) This definition, however, rests on another term that lacks concrete definition - ‘indigenous peoples.’ Anticipating such criticism, Munzer and Raustiala expand upon their definition:

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\(^{18}\) \textit{Ibid} at 24.

a transtemporal cultural group whose members have lived in a subregion of a country or countries prior to conquest or colonization who are a small minority of and to some extent isolated from the main populations of that country or countries, and who have distinctive social, linguistic, and political features.\(^20\)

The focus is therefore on the isolation of communities from mainstream societies. Munzer and Raustiala are not the first to attempt to define the term ‘indigenous people’. The term is, in fact, used narrowly and broadly across the relevant literature.

In its narrower version, it refers to people (including their descendants) who were colonised by European powers in countries where the colonising population remains the dominant group. Oguamanam calls these ‘enclave territories’ and argues that the concept of TK is broader than the narrow construction of ‘indigenous knowledge’.\(^21\) He cites some statistical studies, including one conducted by the United Nations (UN) stating that ‘indigenous peoples,’ in the above-mentioned context, “number between 200 and 300 million people, or about 4 percent of the global population.”\(^22\) Oguamanam argues that the term in its much broadest sense is also used to refer to other ‘local communities’ including those in Africa and Asia that have seen the withdrawal of colonial powers.\(^23\) He concludes that the term should be used in its broader sense to apply “to both the indigenous peoples of the ‘enclave territories’ and … to members of the so-called local communities or non-Western cultures, be they indigenous in the strict sense or not.” [Internal citations omitted] In this sense of the term, ‘indigenous peoples’ describe more than 75 percent of the world’s population and 80 percent of the world’s biodiversity.\(^24\)

\(^{20}\) Ibid at 48.

\(^{21}\) For instance, according to Chidi Oguamanam, enclave territories are “territories where there was no settler withdrawal such as the United States, Canada, Australia, New Zealand, and most of South America.” Oguamanam, supra note 8 at 3 & 23.

\(^{22}\) Ibid at 23.

\(^{23}\) Ibid at 22.

\(^{24}\) For a more detailed discussion of the different versions of defining “indigenous knowledge”, please refer to, ibid at 20–26.
John Mugabe shares Oguamanam’s position that ‘indigenous knowledge’ in its narrow sense does not equate to ‘traditional knowledge.’ Mugabe takes the stance that “indigenous knowledge fits neatly in the traditional knowledge category, but traditional knowledge is not necessarily indigenous.” Put differently, indigenous knowledge is a subset of traditional knowledge. Diagram 1.2 below illustrates the relationship between ‘traditional knowledge’ and ‘indigenous knowledge.’

The WIPO adopts the same position in its report ‘Fact-Finding Missions on Intellectual Property and Traditional Knowledge.’ The WIPO defines TK holders as “all persons who create, originate, develop and practice traditional knowledge in traditional settings and contexts.” To be inclusive of the knowledge of local communities, the term ‘traditional knowledge’ is adopted in this dissertation. The terms “knowledge holders” and “knowledge providers” will be used interchangeably with indigenous and local communities depending upon the relationship each community has with users.

Although there are other alternatives like ‘Aboriginal’, ‘tribal’, and ‘folk’ for describing indigenous people and local communities, they are either limiting or have ‘strong moral load.’ ‘Traditional knowledge’ seems, therefore, to be the most inclusive and most congenial alternative thus far created. TK is also the term most frequently found in the relevant literature and has been adopted by WIPO in several of its documents. Because ‘traditional knowledge’ is ‘less divisive,’ and more inclusive, it has been adopted in this dissertation. The term is also appropriate for the discussion at hand because this dissertation specifically addresses issues related to the creation, use and dissemination of knowledge, rather than, for instance, indigenous people’s rights. Despite

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26 Ibid at 98.
28 Ibid at 26.
29 Oguamanam, supra note 8 at 24.
30 Ibid.
the attempt to clearly define the term ‘traditional knowledge,’ it should be noted that the definition adopted is fluid and should be considered a working definition.

Diagram 1.2: This dissertation focuses on the inclusive term ‘traditional knowledge.’

Similar to knowledge holder communities, knowledge users can be diverse. Users have been defined as “individuals or entities that actually import and utilise genetic resources whether for commercial or purely scientific purpose.”31 Although this definition, following that of the CBD, focuses on genetic resources, it could be used to define users of TK as well. Consequently, the terms refer to diverse groups of individuals or firms with differing backgrounds and interests (commercial or non-commercial) that use TK to further their goals. This excludes members of the

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TK holder community who use TK. The concept of ‘users’ is used to refer to those outside the TK holding community.

1.2.3 What is the difference between ‘traditional’ and ‘Modern’ knowledge?

One key discussion of the definition of TK focuses on difference, in terms of world views, between the globalised Western philosophy and traditional/indigenous beliefs. Since understanding the relationship between these two knowledge systems is important for subsequent discussions, a brief analysis of this relationship seems useful at this point. That said, and as one can deduce from the above attempts at defining TK, delimiting the scope of both TK and Western knowledge systems is a ‘contentious exercise.’ Additionally, the attempt to cluster knowledge into ‘traditional’ and ‘Western’ “does not in any way suggest that the West has no indigenous or ‘folk’ knowledge of its own…what is today recognised ‘as scientific knowledge of the natural world was…constituted during the eighteenth and nineteenth centuries’ in a way that absorbed some pre-existing European local folk knowledge and practices.” Since Western knowledge has, however, become hegemonic and claims to be a ‘modern’ or ‘scientific’ comparing it with the loosely defined traditional knowledge systems may be fruitful.

Given the diversity of indigenous and local communities worldwide, discussing crosscutting issues as they relate to such communities becomes very difficult. Scholars have, however, identified common elements that most traditional communities operate under. Understandably these elements tend to be general. For example, research conducted by the International Institute for Environment and Development (IIED) identified common elements shared by most traditional communities about TK. These include a ‘holistic worldview’ that considers human beings to be part of an interconnected web of relationships and responsibilities together with ‘Spiritual beliefs’

32 Oguamanam, supra note 8 at 14.
33 Ibid.
34 International Institute for Environment and Development (IIED), Protecting Community Rights over Traditional Knowledge Implications of Customary laws and practices: Key findings and recommendations 2005-2009 (International Institute for Environment and Development (IIED), 2009).
where everything – ‘living’ and ‘non-living’ has a spirituality that should be honoured. The report also identifies the common values of ‘reciprocity’ and ‘equilibrium’ in the relationship between society and nature. Also shared by many traditional communities is the notion of ‘duality’, which reflects the belief that “everything has a complementary opposite.” This last shared value allows room for traditional knowledge systems to recognise other types of knowledge systems such as the Western system, something the latter system is at times criticised for lacking.

The anthropological literature seems to suggest that there are key factors that distinguish TK to Western knowledge. In a frequently cited publication, a Canadian anthropologist, Martha Johnson, lists key features that define TK in the anthropological literature. According to Johnson, TK is:

- Orally recorded and transmitted, and learned through observation and hands-on experience;
- Based on the understanding that all parts of matter have a life force;
- Based on the view that human life is not superior to animate and inanimate elements
- Holistic and interconnected, and intuitive as opposed to analytical
- Mainly qualitative rather than quantitative
- Based on data generated by resource users rather than a specialised group of researchers
- Based on diachronic data which is based on a long time series of information on one locality

35 Ibid at 5.
36 Ibid.
37 Ibid.
38 Oguamanam, supra note 8 at 15.
Rooted in a social context that sees the world in terms of social and spiritual relations between all life-forms.

Based on cumulative and collective experiences which are checked, validated, and revised daily.\textsuperscript{40}

Given that the above list is a result of a survey of the anthropological literature on the subject, one could claim it provides an authoritative list. However, some of the features used to distinguish TK from Western knowledge may not be applicable to all TK holder communities, and some are misleading generalisations at best. For instance, claiming that TK is qualitative while Western knowledge is quantitative is not justified because a considerable portion of Western knowledge relates to qualitative ways of knowing. A good example of this is the knowledge that results from fields of scientific research that adopt qualitative research methods. Despite the challenges of using the above-listed features to clearly delineating TK from Western knowledge, some of these features are useful tools in crafting a somewhat fluid definition of TK.

Generally, traditional knowledge systems focus on communal and holistic relationships while the Western knowledge system focuses on the individual. As James Boyle described it, the Western system is “constructed around a vision of individual, transformative, original genius.”\textsuperscript{41} Differences in perspective lead to differing ways of life. The predominantly oral method of knowledge generation and transmission, the observational and hands-on process of learning, and the cumulative development of the knowledge may be noted as major features of TK that distinguish it from Western knowledge. The oral-written distinction is important for the discussion at hand and will be further analysed in the following chapter. Although the above-discussed differences exist, the distinction is highly fluid and should therefore not be taken as concrete criteria for labelling a knowledge system as ‘modern’ or ‘traditional.’

\textsuperscript{40} \textit{Ibid} at 7–8.

Traditional knowledge systems have been rejected as inferior in the past. In recent years, however, various customary rules and principles have been studied and found to be informative for the modern way of life. Recent literature on the subject of knowledge systems tends to embrace the plurality of worldviews and their co-existence. For instance, Oguamanam argues:

The notion of knowledge is a contested one, whether investigated in sociological, philosophical, jurisprudential, or historical terms. The term ‘scientific knowledge’ is ambiguous for the simple reason, among others, that the world ‘science’ is often used as a synonym for knowledge. Science is generally considered a way of knowing. Arguably, every knowledge system with a systematic and formulated basis is scientific. [Internal citations omitted]

Indeed, some of the literature on TK attempts to show the ‘systematic’ ways of knowing, innovating, protecting and transmitting knowledge and in that sense, TK can be said to be ‘scientific.’

Although there is no formal classification of the knowledge systems that indigenous and local communities hold, scholars have attempted to group TK into different categories. These groupings seem to be an attempt to follow the grouping of knowledge systems in the Western world. TK has been clustered into the following sub-groups in the literature: traditional medicinal knowledge (TMK), traditional agricultural knowledge (TAK) and traditional ecological knowledge (TEK). Such classification is not, however, exhaustive. Some commentators, for instance, include other clusters such as “traditional knowledge of lifestyle … traditional architectural knowledge and

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42 There have been numerous studies into customary rules and principles related to traditional knowledge and biodiversity conservation. The work of the secretariat of the CBD, the IIED report and the WIPO Fact-Finding Missions are excellent examples of the increasing interest in customary laws in this area.
43 Oguamanam, supra note 8 at 14.
Moreover, the categorization is not always clear cut because elements of a sub-group of TK can be part of another sub-group. For instance, traditional knowledge of a certain plant could be called traditional ecological knowledge, traditional agricultural knowledge and traditional medicinal knowledge depending on the focus of the given study.

It is worth noting here that attempts at clustering of TK into different groups face strong opposition from some scholars and indigenous peoples. As highlighted in earlier sections of this chapter, TK is considered by many communities to be part of their identity or ‘peoplehood.’ TK is thus considered to be an element of a community’s culture that is intertwined with other cultural features to make up the community’s identity. Thus, some communities and scholars consider the categorising TK as a feature of a culture distinguished from other parts to be a risky endeavour that would take TK out of the context in which it is developed, reducing its value and meaning in the process. Despite such objections, a selective discussion of TK as it relates to specific issues, such as the use of traditional medicinal knowledge in drug discovery, is necessary and justified. It is with such understanding that the below section discusses traditional medicinal knowledge and the reasons for focusing on such area.

This section has analysed the definition of TK from three angles. It has examined what ‘traditional knowledge’ covers, its relationship to ‘modern’ or ‘Western’ knowledge, and the identities of the knowledge holders. Now we turn to an examination of traditional medicinal knowledge – the area of TK given special emphasis in this dissertation.

1.3 Traditional Medicinal Knowledge (TMK)

This dissertation focuses on just one part of TK: traditional medicinal knowledge (TMK). We will start with the reasons for choosing TMK over traditional agricultural knowledge (TAK) and

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traditional ecological knowledge (TEK) as our area of focus. We will then discuss the definition of TMK and provide some popular examples.

There are several good reasons for adopting TMK as the area of focus. First, as discussed early in this chapter, the concept of TK itself is an issue of debate. The term is used to refer to a wide variety of subjects, and there are disagreements related to its scope. Therefore, discussing TK as a whole, including traditional agricultural knowledge (TAK) and traditional ecological knowledge (TEK), would likely require generalisations that make difficult any detailed analysis of subjects as narrow as TMK. A focus on one area of TK allows for a detailed and coherent analysis of such area.

Second, TMK is at the heart of domestic and international discussions and activities on TK protection as a whole and under IP laws in particular. Many of the issues that give rise to discussions of TK protection (including cases of ‘biopiracy’) emanate from the use of TMK in drug discovery. The various national and international initiatives that attempt to integrate Western and non-Western medical systems are evidence of the importance of the subject matter. The World Health Organization’s (WHO) work on integrated medical systems project is an example of one such initiative.

It should be noted here that TMK is used in two ways. It is used by knowledge holder communities and outsiders as an independent knowledge system to treat a variety of diseases. In addition to such independent use, TMK is used as an input in modern medicine. This dissertation is concerned

46 Oguamanam, supra note 8 at 153.
47 As will be discussed in further detail later in this chapter, the term bio-piracy has been used to describe cases in which patent claims have been made over inventions that are allegedly based on traditional knowledge. See Section 1.9
48 One of the stated goals of the World Health Organization is the integration of informal medical systems into the formal system. The pressure for adopting the 2002-2005 strategy came from the increasing use of TMK in various national jurisdictions. See World Health Organization, WHO Traditional Medicine Strategy: 2002-2005 (World Health Organization, 2002).
49 The work that the World Health Organization (WHO) has been conducting in the area of traditional medicinal knowledge is discussed under section 1.8 below.
with the second types of uses of TMK. The focus on the use of TMK as an input is because the issues involved in the independent use of TMK relate to improving the efficacy and efficiency of TMK rather than the ownership of such knowledge. Since the current research is interested in the intellectual property implications of TMK, and since such issues stand out when outsiders use TMK as an input in modern medicine, these types of uses are focused on in this dissertation.

The focus on TMK in this dissertation is not intended to mean that all of the discussions throughout this dissertation apply solely to TMK. Some of the general analysis is also likely to be applicable to other areas of TK. For instance, the discussions in the latter part of the thesis on the impact of legal intervention for the documentation and disclosure of TK, the law and economics analysis of information goods, and the international dialogue on TK are applicable to other areas of TK. In such cases, reference is made to TK in general, as opposed to TMK. Where analysis is limited to TMK, reference is made only to TMK.

In light of the above, some discussion of the definition of the term now seems fitting. Though alternative terms such as ‘eastern medicine,’ ‘bush medicine’, ‘alternative medicine,’ ‘complementary alternative medicine’ and ‘shamanic knowledge’ are used in various documents – for the sake of consistency - the term ‘traditional medicinal knowledge’ is used throughout this dissertation.

Though a subset of TK, TMK is no less challenging to define, Commentators have, however, proposed some useful definitions. Mamadou Koumare defines ‘African’ traditional medicinal knowledge as:

The total body of knowledge, techniques for the preparation and use of substances, measures and practice in use, whether explicable or not, that are based on the sociocultural and religious bedrock of African communities, are founded on personal experiences and observation handed down from generation to generation, either verbally or in writing, and are used for diagnosis, prevention, or
elimination of imbalances in physical, mental or social well-being.\textsuperscript{50}

Although Koumare defined TMK in the African context, the definition does not include elements unique to the African continent. The openness of the definition makes it applicable to the TMK of other indigenous peoples and local communities in other parts of the world. The above-quoted definition is fruitful for this dissertation because it covers a wide range of TMK that is relevant for bioprospecting projects.

The WHO takes a slightly different position. According to the WHO traditional medicine refers to “…diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.”\textsuperscript{51} The WHO acknowledges that this inclusive definition is adopted out of necessity and that defining the concept is problematic because of the differences between the various types of TMK and the variety of activities it might represent.\textsuperscript{52} Although, the above ‘working definition’ includes neither the words ‘traditional’ nor ‘indigenous,’ it is logical to deduce from the context that the definition does refer to the same body of knowledge. The openness of WHO’s definition to diverse methods of providing traditional medicine is especially useful to discussions in this dissertation.

These definitions provide a framework for the discussions to follow. A general definition covering diverse manifestations of TMK preferred, to support our comprehensive discussion of this selected area of traditional knowledge. Further, this dissertation adopts the working definition of ‘traditional medicinal knowledge’ to be ‘the medicinal know-how, skills, innovations, practices and beliefs of indigenous peoples and local communities.’

\textsuperscript{51} World Health Organization, \textit{supra} note 48 at 7.
\textsuperscript{52} \textit{Ibid.}
Some examples might be useful in describing traditional medicine. Among various traditional medical systems, the South Asian Ayurveda system is considered one of the oldest and most comprehensive. It is also one of the most documented traditional medical systems as the knowledge is documented in the *Vedas* (books of knowledge) dated to 1000 B.C.E.\(^53\) The Unani medical tradition originated from the ancient Arabic civilizations and is today practiced in India and Pakistan.\(^54\) Traditional Chinese medicine, whose origins trace back to 1800 B.C.E, is celebrated as the “crystallization of Chinese people’s wisdom and experience.”\(^55\) Other traditional medical systems are also found in Africa, Latin America, and North America. The common elements in these traditional medical systems are their use of natural substances such as plants, animals, and minerals as a base together with their spiritual nature with strong connections to many of the major religions.

Traditional medicines are also usually administered ceremoniously. Additionally, ethnopharmacological ingredients are held sacred beyond the context of ceremony and throughout daily life. It is not that every member of a knowledge holding community has full access to TMK and is able to practice it. In contrast to other types of traditional knowledge such as agricultural, ecological or architectural knowledge, TMK is relatively restricted and hierarchical. TMK is usually held by traditional healers, in some communities predominantly women, who have the knowledge and skill to execute the ceremonial and substantive provision of TMK.\(^56\) As such, TMK might be more secretive than other types of TK. A given community may have herbalists, bone setters and religious healers who have apprenticed with other healers or are the descendants of other healers.\(^57\) TMK is, thus, usually transferred in a controlled manner and evidence of

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attempts at keeping the knowledge secret can be found in certain communities.\(^{58}\) At least some of the rationales behind the hierarchy and secrecy seems to be an assurance that powerful medicinal knowledge does not fall into the hands of an ‘uninitiated’ community member, and not to encourage the personal accumulation of wealth.\(^{59}\) The general worldview regarding TMK is one of communal ownership with regulated access.

### 1.4 Relevance of the Definition of TK and TMK

Before concluding our discussion of definitions for TK and TMK, it is useful to highlight how the choices made in defining terms affect the discussion throughout this dissertation. The key points of TK thus far discussed include: that a narrow definition has been adopted in this thesis and in many international entities; that the holders of TK include both indigenous peoples and local communities; and that TK may be distinguished from ‘Western’ or ‘Modern’ knowledge based on some key features, such as its documentation through oral means and its development through incremental and communal processes.

This dissertation defines TK narrowly as ‘the know-how, skills, practices, innovations and learnings of indigenous peoples and local communities.’ The narrow definition is adopted for good reasons. A detailed discussion of all the features of TK in its broad definition could not be provided given the time and space limitations of the dissertation. For instance, since a broader definition of TK involves diverse features ranging from technical know-how to traditional music and from folklore to aboriginal drawing and sculpture, a coherent and nuanced analysis would require considerably more time and resources. A narrowed definition of TK more readily allows for detailed analysis. Moreover, a narrow definition is the one most frequently used in the literature, including in discussions at the WIPO. Further, the core argument of this thesis is for the establishment of an economic rationale for the protection of TK. Traditional know-how lends

\(^{58}\) Adamu, supra note 57 at 54.

itself more easily to discussions of economic value than cultural expressions in which aesthetics and artistic values play a major role.

The term ‘traditional knowledge’ has also been analyzed in terms of the two types of communities that create and sustain it: indigenous peoples and local communities. It has been noted that, since the objective of this dissertation is to provide a legal framework that could effectively regulate TK at a global level, the inclusive term ‘traditional knowledge’ is preferred than ‘indigenous knowledge’ or other narrower terms. This will allow comprehensive examination of the common features of indigenous peoples and local communities as they relate to the regulation of TK.

We have also here distinguished TK from the Western knowledge system. While acknowledging that such a division is rough and general in nature, the section has outlined some key features that can distinguish the two. That TK focuses on communal and holistic approaches while Western knowledge focuses on the individual is one key point of difference. Another feature is the predominance of oral methods of knowledge transfer as opposed to the written transmission favored in the in West. Identifying these differences is essential to the analysis in this dissertation. The individual-communal divide is one of the key points that has resulted in TK falling outside the legal protection provided to elements of Western knowledge systems. Furthermore, the need to codify TK is the impetus for this dissertation.

We have discussed what is meant by ‘traditional medicinal knowledge’ (TMK) and the reasons for selecting TMK as the focus of this dissertation. The rationale for the selection of TMK as the area of focus are the preference for a narrow scope that would allow for a detailed analysis and the proposal of concrete solution; the existing predominance of TMK in the scholarship and deliberations; and the fact that many TK documentation on which this dissertation relies are on TMK. Diagram 1.3 illustrates the different relationship between TK, TMK, and other parts of TK.
Given that the two core concepts of TK and TMK have been introduced, it is fruitful to turn to an analysis of what the relationship is between TK and formal (conventional) IP laws. With an emphasis on TMK, the following section examines the challenges and opportunities that arise when using formal IP laws to extend protection to TK.

1.5 The Relationship between Intellectual Property Law and TK

Considerable scholarship focuses on the potential and challenges of using intellectual property laws to protect TK. Despite arguments made by some commentators, the recent consensus seems to be that IP laws provide little, if any, protection of TK. The detailed features of IP laws differ from one jurisdiction to another. The core requirements seem, however, to be the same or at least similar most every jurisdiction. These similarities in the core requirements of patent laws have been further harmonized by the requirements of the TRIPs agreement which list novelty, inventive
step and industrial applicability as the three core requirements of patent laws. Thus, a general analysis of how patent laws relate to TK can reasonably be made. The following analysis focuses mostly on how patent laws relate to TK since the way TK has been defined in this dissertation (i.e. as know-how) relates mostly to the subject matter of protection under patent laws.

As stated earlier, most recent scholarship views patent laws as providing little protection to TK. The challenges of applying patent law to TK can be seen in one of two ways: with a general perspective on purpose and orientation of the law or, in a specific sense, with a view to the details of such law.

In the general sense, there is a difference in the orientation of patent laws and TK. The focus of patents is rewarding the individual(s) involved in an invention, which is based on the Western preference of providing rights to individual citizens. This orientation can be contrasted with the more communally oriented TK. The divide can be linked to the Western origins of patent law and the fact that indigenous peoples and local communities did not take part in its development. This is not to say that there is no flexibility within patent law. Patent laws do have space for co-inventorship when more than one individual is involved in the process of the invention. As will be discussed in the following paragraphs, however, the communal and intergenerational innovation that produces TK does not fit well with such a framework. Patents also focus on the

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60 Article 27 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights of the General Agreement on Tariffs and Trade, 15 April 1994 [TRIPs] The provision reads as follows: “... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” [Emphasis added] Footnote 5 of the same article provides that “[f]or the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.


62 There are several ancient practices, including in ancient Greece, which resemble current day intellectual property rights. The Venetian statute of 1474 and the 1624 Statute of Monopolies in England are considered to be the earliest documented legislations granting patent-like rights. For a historical account of the development of IP law, see Brad Sherman, The making of modern intellectual property law: The British experience, 1760-1911 (New York: Cambridge University Press, 1999).

final step in the process of the development of an invention. Boyle’s statement that patent systems focus on the “individual, transformative, original genius”\(^{64}\) rightly encapsulates this orientation.

The individual-communal division should not, however, be overstated.\(^{65}\) As rightly noted by Coenraad J. Visser, such a divide is a “slight oversimplification.”\(^{66}\) There is diversity in the customary laws of indigenous peoples and local communities where some of them are oriented towards the granting of individual rights and duties which may be equated to intellectual property.\(^{67}\) As Graham Dutfield identifies, instead of general individual-communal conflicts, patent laws do not work for TK because some TK holder communities envision collective responsibilities to be inseparably tied to individual rights under customary laws.\(^{68}\) This combination of collective responsibilities with individual rights may have particular strength in the area of TMK. As discussed earlier, TMK is in most communities held by a member or members who are thought worthy of the knowledge. This does not, however, mean that such individuals enjoy individual rights in the TMK. It is common to tie access privileges to a collective responsibility for knowledge use and transfer.

Several other features of the patent system may conflict with TK. One such feature is the available remedy. Generally, the common remedy available for a patentee in the case of infringement by others is the economic award of damages. Although an injunction may also be granted, recent developments have limited the granting of injunction for patent infringement.\(^{69}\) In addition to economic remedies, knowledge holder communities may be interested in receiving attribution for

\(^{64}\) Boyle, *supra* note 41 at 128.

\(^{65}\) Dutfield, *supra* note 59 at 503–504.

\(^{66}\) Visser, *supra* note 61 at 211.

\(^{67}\) Dutfield, *supra* note 59 at 502–503.

\(^{68}\) Ibid at 503.

\(^{69}\) eBay Inc et al, v MercExchange, LLC, (2006) S. Ct. 126 S. Ct. 1837 (This case from the United States Supreme Court, for instance, shows the move from granting permanent injunction one patent infringement is found to a four-step analysis to determine if and when the grant of permanent injunction is justified); See generally, Bernard Chao, “After eBay, Inc. v. MercExchange: The Changing Landscape for Patent Remedies” (2008) 9:2 Minn J Law Sci Technol 543. (Examining the trend in which court have resist granting permanent injunction even after finding willful patent infringement).
being the source of TK and in restricting others from engaging in offensive uses of their TK. As a result, even if some TK may qualify for patent protection, knowledge holder communities may not be interested in participating in such system.

Furthermore, knowledge holding communities consider TK to be an inherent part of their identity. Commentators have claimed that TK is an essential part of the ‘peoplehood’ of such communities, and thus many communities may not accept term limits on their rights over TK. However, the protection that patents provide is time-limited. In most jurisdictions, patents have a 20-year term from the date of application/issue. Commentators and knowledge holder communities view this time limit as a major feature of patent law that is inappropriate for TK protection. Additionally, in a more pragmatic sense, even if patents adequately protected TK, knowledge holder communities may lack the resources and expertise to make full use of the patent system. For instance, knowledge holders may not be able to describe their knowledge in the form required in patent applications including patent specification and claims. Patent applications usually require highly technical knowledge and considerable financial resources.

As for the particulars of patent laws, TK, for the most part, fails to meet the three core requirements of patentability. Patent laws require that an invention be new (novel), non-obvious (have an inventive step), and be useful (industrially applicable). Although these terminologies developed in different jurisdictions and their meanings do not necessarily overlap with each other, they refer to similar concepts that have been used synonymously in many instruments, and, so, the below analysis follows such practices.

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72 Roht-Arriaza, supra note 63 at 264.
73 Dagne, supra note 71 at 4.
74 For instance, see Article 27 (2) and footnote 5 of the most authoritative international instrument on patent laws, TRIPs, supra note 65.
Newness or novelty requires that the claimed invention not be anticipated by ‘prior art.’ Prior art can generally be defined as any publicly accessible knowledge, as of the time of a patent application, which is relevant for a claimed invention. If an invention has been disclosed or anticipated by a prior art reference, then it fails the newness (novelty) requirement, and the claim will be rejected.\(^75\) Most TK develops incrementally over generations, and it is, therefore, hard or impossible to select an individual or individuals who can claim to have single-handedly developed a particular feature of the knowledge. This inter-generational and incremental nature will invalidate the patentability of most TMK, which is usually held by an individual or a few individuals in a community.\(^76\) By the time a traditional healer applies for a patent, the TMK may well have been in practice for generations thus failing to meet the newness (novelty) requirement.

An invention is also required to be non-obvious (US and Canada) or to have ‘inventive-step’ (most other countries).\(^77\) This is taken to mean that a claimed invention should not be obvious to a Person Having Ordinary Skill in the Art (or the field of study) (PHOSITA). Given the fact that TK in most instances is not technically advanced or complex, this requirement may also become a challenge for most TK. More relevant for TMK, the ‘product of nature’ doctrine in patent law excludes the patenting of discoveries of natural phenomena.\(^78\) The ‘product of nature’ doctrine will, therefore, exclude most TMK from patentability because “medicinal plants in their natural state, or even diluted or otherwise processed,” are not patentable.\(^79\)

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\(^75\) For instance, for US patent law see 35 U.S.C. § 102 Conditions of Patentability: novelty and loss of right to patent; For Canadian patent law, see, An Act Respecting Patents of Invention, RSC 1985 C P-4 [Patent Act R.S., c. P-4, s. 1.] s. 28.2.

\(^76\) Roht-Arriaza, supra note 63 at 263.

\(^77\) For US patent law see 35 U.S.C. § 103 Conditions of Patentability: non-obvious subject matter; For Canadian patent law see Patent Act R.S., c. P-4, s. 1., supra note 75 s. 28.3.

\(^78\) For example, for a recognition of the “product of nature” doctrine in US case law, see Funk Bros Seed Co v Kalo Inoculant Co, 333 US 127 (United States Supreme Court); For a scholarly discussion of the scope of the “product of nature” doctrine under US patent law, see, Michael D Davis, “The Patenting of Products of Nature” (1995) 21 Rutgers Comput Technol Law J 293.

\(^79\) Roht-Arriaza, supra note 63 at 263.
Lastly, inventions are expected to be useful or be industrially applicable. There is usually a low threshold to meet as it requires only that a claimed invention have some utility and that it ‘works’ i.e. it does what it promises to do. As described in further detail below, TMK has considerable value both as an independent source of health care and, more relevantly to this dissertation, as an input in bioprospecting projects. Even if community members are unable to explain how a certain TMK does what it does, it is sufficient that they show that it has some use. Consequently, some TMK could be expected to fulfill the usefulness or industrial applicability test. Although commentators have argued that the term ‘industrial applicability’ might exclude informal or traditional sectors, such as those where TK is involved, such interpretation does not seem warranted given the term’s synonymous use with the term ‘usefulness.’ Despite being able to meet this last patentability requirement, as discussed in the preceding paragraphs, TK hardly meets the newness (novelty) and non-obviousness (inventive step) requirements. As a result, patent laws in their current form are not promising legal tools in the protection of TK.

The preceding discussion is not to say that TK is a static, unchanging, pre-existing body of knowledge. On the contrary, as commonly understood by scholars, TK is a dynamic body of knowledge evolving through time to meet the needs of knowledge holder communities. What makes TK ‘traditional’ is the fact that it is created, developed and transmitted through traditional means such as experiential observation, kinship or apprenticeship experiences, predominantly through oral transmission and the like.

In this sense, TK differs from what is referred to under patents as ‘prior art.’ As stated earlier, prior art refers to any publicly available knowledge before the timing of the filing of a patent which is relevant for a claimed invention. Thus, the reference to a particular time ‘before the filing

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81 Roht-Arriaza, supra note 63 at 264.
82 Fulvio Mazzocchi, “Western science and traditional knowledge: Despite their variations, different forms of knowledge can learn from each other” (2006) 7:5 EMBO Rep 463 at 463.
of a patent’ seems to refer to a static body of knowledge. The dynamic nature of TK makes it different from ‘prior art.’ Furthermore, even if some TK is considered to be already in existence, it does not necessarily follow that it is ‘publicly accessible.’ In some instances, knowledge holder communities successfully hold TK secret. This is frequently the case with TMK where most communities seem to have traditional procedures for keeping it a secret, including by practicing healing ceremonies at secluded places; using various methods of secretive cultural ceremonies when administering treatments. Additionally, the remoteness of some knowledge holder communities, the oral nature in which most TK exists in and the language differences between knowledge holder communities and users, make TK inaccessible (despite some of it being publicly available).

As a result of the dynamic nature of TK, it could, at times, be seen to meet the requirements of conventional IP laws. It has been argued, for instance, that small advances in TMK could qualify for petty patents in jurisdictions that provide such rights. Since petty patents protect inventions that are novel and useful but do not satisfy the non-obviousness (inventive step) requirement, some incremental advancements in, say, the extraction of compounds from therapeutic plants could qualify for protection under petty patents. If a certain TK qualifies for protection under conventional IP laws and if it is in the interest of knowledge holder communities or a member of such community, applications for petty patents could be made.

There is, in fact, considerable literature calling for TK protection advocates not to ignore the potential of existing laws for meeting the needs of knowledge holder communities, albeit in a limited way as discussed above. Peter Drahos and Susy Frankel, argue that most TK would benefit from trademark types of IP protection that provide a “right to distinguish a product in

85 Ibid.
87 Taubman, supra note 4; Peter Drahos & Susy Frankel, Indigenous People’s Innovation: Intellectual Property Pathways to Development (ANU E Press, 2012) at 23–25.
commerce” more than from a patent-like right that “confer origination rights over a product.”\textsuperscript{88} This claim seems to hold some truth given that indigenous peoples and local communities register many trademarks yet make few patent applications. The relative ease of registering a trademark right compared to a patent right might partly account for the difference. In light of the above, it is unlikely that patent laws have the potential to meet the needs and expectations of knowledge holder communities.

1.5.1 Customary Rules Relating to TK:

Not only do knowledge holder communities innovate within traditional settings, some also have customary law and norms regulating TK. There are customary protocols on how certain TK is shared with community members and outsiders.\textsuperscript{89} This may range from rules stating that a certain TK element is to be accessible to all (including outsiders) to norms limiting TK even within the community. For instance, in some communities, although certain intellectual property has been created by ancestors, current members of the community might be the ones given the power to manage or re-create such ‘properties.’\textsuperscript{90} As stated earlier, in many communities, traditional medicinal knowledge is mostly kept secret and is shared through apprenticeship-type relationships.\textsuperscript{91} Despite the existence of some social obligations outlined in customary rules, such systems have not been recognized in modern intellectual property laws.

As a result of this lack of recognition, some commentators have called for legal pluralism in conventional IP laws.\textsuperscript{92} The adoption of a pluralistic perspective seems reasonable given the diversity of interests and world views involved in TK, particularly in the use of TMK in bioprospecting projects. Implementing diverse rules relating to the protection of TK will,

\textsuperscript{88} Drahos & Frankel, \textit{supra} note 87 at 26.
\textsuperscript{89} Dutfield, \textit{supra} note 59 at 501–502.
\textsuperscript{90} Dean Ellinson, “Unauthorised Reproduction of Aboriginal Art” (1994) 17:2 Univ New South Wales Law J 327 at 331.
\textsuperscript{92} Taubman, \textit{supra} note 4 at 551; Drahos & Frankel, \textit{supra} note 87 at 2.
however, be a herculean task. Legal pluralism among Western jurisdictions with great similarity is hard as it is.\footnote{Brian Z Tamanaha, “Understanding Legal Pluralism: Past to Present, Local to Global” (2008) 30 Syd Law Rev 375 at 381–390.} Attempting to bring together conventional IP laws with customary rules relating to the regulation of TK will be harder still. Despite this challenge, if any proposed framework for TK protection is to bring about meaningful change for stakeholders involved, there should be a clear rule regarding how the two systems might work together. In terms of TK that fully meets the three requirements of patent laws, IP rules could allow customary norms to regulate which person(s) within a community will be the ‘owners’ of a right.

Now that the core concepts in the discussion on the protection of TK have been outlined, and the relationship between IP laws and TK examined, the following section discusses the relevance of TMK in ‘modern’ societies. It defines concepts such as ‘bioprospecting’ and ‘biodiversity’ and shows how TMK is used in the ‘modern’ world in the process of developing new drugs. The following section helps illustrate the problem caused by the lack of legal protection of TMK from the bioprospecting perspective.

### 1.6 Bioprospecting and Traditional Medicinal Knowledge

Bioprospecting is the R & D process conducted in search of new drugs from biological resources. Bioprospecting involves considerable experimentation because research in the ‘unpredictable arts’ involves significant risks. The term ‘unpredictable arts,’ as opposed to applied arts, refers to fields in chemistry and biology such as biotechnology, which involve significant risk of failure.\footnote{For a description of the term “unpredictable arts,” See, Section 2164.03 - Manual of Patent Examining Procedure: Relationship of Predictability of the Art and the Enablement Requirement (United States Patents and Trademarks Office, 2014).} Risks arise because of the inherent unpredictability of chemical and biological reactions; because they are new fields of research and little is known about them;\footnote{For a discussion of case law in the area of the unpredictable arts, See Sean B Seymore, “Heightened Enablement in teh Unpredictable Arts” (2008) 56 UCLA Law Rev 127 at 137–8.} as a result of the lack of knowledge of causes of illnesses; and because of the lengthy and rigorous regulatory approval.
process involved. As a result of this unpredictability, it is a highly costly endeavor. To mitigate these risks, pharmaceutical and biotechnological companies have increasingly looked to the traditional medicinal knowledge (TMK) of indigenous and local communities.\textsuperscript{96} Referred to as ‘ethnopharmacology,’ or ‘ethnomedicine,’ this field has resulted in a drastic reduction in the time and cost it takes to discover a new drug.\textsuperscript{97} The use of TMK in the drug development process can especially make the initial stages of selecting and extracting active ingredients much easier than alternative methods. Instead of a large sample of resources, researchers can use TMK as a guide in selecting the most promising genetic resources that have a potential for cure.

1.6.1 The Value of TMK

The value that TMK has is discussed from various sources. For instance, one study has shown that the use of TMK increased the chances of getting a preliminary hit\textsuperscript{98} in plant screening from 6% to 25%.\textsuperscript{99} Other research has revealed the predictive role that TMK plays in drug discovery.\textsuperscript{100} It has been proved that 80% of the drugs that were examined in the research have the same or similar use traditionally.\textsuperscript{101} Although challenged by some, the value of TMK in modern drug discovery has been repeatedly demonstrated. Perhaps the below quote from an article in the New


\textsuperscript{98} “Preliminary hit” is the compound that is selected from a large number of compounds as a result of its phenotype or process which is relevant for the disease being researched. The compound would still have to go through validation and other tests in the drug discovery process. Benoit Deprez & Rebecca Deprez-Poulain, “Hit-to-Lead: Driving Forces for the Medicinal Chemist (Guest Editor: Benoit Deprez and Rebecca Deprez-Poulain” (2004) 4:6 Curr Top Med Chem i; Rebecca Deprez-Poulain & Benoit Deprez, “Facts, figures and trends in lead generation” (2004) 4:6 Curr Top Med Chem 569.


\textsuperscript{101} Fabricant & Farnsworth, \textit{supra} note 96.
York Times shows a specific case in which TMK has played a significant role in the attempt to find a cure for AIDS.

In a field study in the rain forest in Belize, Dr. [Michael] Balick [director of the Institute of Economic Botany at the New York Botanical Garden] compared using a random collection of plant species with an ethnobotanical approach, in which only the plants that local people say have medical uses are collected. […]

Of the 20 plants collected on the shaman's advice, five killed the AIDS virus but spared the T cells. But of 18 plant species gathered randomly, just one did so.  

Although much more research and development may have to be made after TMK is used, the role TMK plays is very crucial. Dr. Balick, who received a $2.5 million contract from the National Cancer Institute to conduct the research has expressed concerns over the alarming rate of TMK loss.  

In addition to the value of TMK as an input to the modern drug discovery process, it is used independently to treat a variety of illnesses. Although the focus of this dissertation is on the use of TMK to improve modern drug discovery, the value that TMK has as an independent source of medical treatment may add to the importance of documenting this body of knowledge. That said, the main points of this dissertation do not depend on the efficacy and value of TMK as an independent source of health care. Therefore, even the most skeptical observer of the use of TMK may find value in its documentation and use in the modern drug discovery process.

\[\text{Goleman, supra note 91.}\]
\[\text{Ibid.}\]
In order to generally highlight the independent value of TMK, it may be helpful to provide some data on the global use of TMK. The World Health Organization has summarized government and non-governmental reports showing an increase in the use of TMK and alternative medicine.\textsuperscript{104} It is estimated that 70-80\% of the population in developing countries depends on traditional health care systems.\textsuperscript{105} The use of TMK is not restricted to the developing world, a significant percentage of the population in developed countries uses some form of traditional health care systems.\textsuperscript{106} The estimated global market for herbal medicine in the year 2000 was at $43 billion\textsuperscript{107} and the market for plant-based pharmaceuticals in 1990 as evaluated by OECD was $61 billion.\textsuperscript{108} There seems to be increasing recognition of the potential that this body of knowledge holds.\textsuperscript{109}

As mentioned earlier, however, the core thesis provided in this dissertation focuses only on the value that TMK has in the biopharmaceutical industry. TMK is useful to the biopharmaceutical industry in two ways: “as an input and as a method of conserving valuable biodiversity.”\textsuperscript{110} On the one hand, it serves as an input because it reduces the “marginal cost of developing a new drug and increases marginal revenue.”\textsuperscript{111} On the other hand, since the body of knowledge is highly dependent on biodiversity, continued use of traditional medicinal knowledge means that indigenous and local communities will conserve biodiversity resources through their age-old practices.

\textsuperscript{105} Ibid at 2–3.
\textsuperscript{106} The World Health Organization estimates that the following percentage of the population in each country has used some form of alternative medicine at least once: 48\% in Australia, 50\% in Canada, 42\% in USA, 40\% in Belgium, 75\% in France and 90\% in the United Kingdom. See \textit{ibid} at 3.
\textsuperscript{107} Ibid.
\textsuperscript{108} Dutfield, \textit{supra} note 59 at 504.
\textsuperscript{111} Ibid.
As discussed in the previous section, traditional medicinal knowledge (TMK) refers to the “knowledge, skills and practices” of indigenous and local communities. This body of knowledge is highly dependent on biodiversity because indigenous and local groups rely heavily on biodiversity for survival. In both traditional and modern medicine the therapeutic value of plants takes a considerable share of the input. As such, the discussion below refers to TMK related to plants with therapeutic elements, although it does not exclude TMK related to other sources such as other organisms and minerals. Despite the dominance of plants as sources of TMK, knowledge related to these other sources may at times be just as useful in bioprospecting processes.

1.7 Biodiversity and Traditional Medicinal Knowledge

The purpose of this section is to show the relevance of biodiversity and its loss to TK in general and to TMK in particular. Biological diversity “means the variability among living organisms from all sources” and it includes “diversity within species, between species and of ecosystems.” It is essential “for maintaining life sustaining systems of the biosphere.” However, the current rate of biodiversity loss is alarming: in the past, such loss has been within the range of “1 – 10 species per million per year” and it has now increased to “hundreds or low thousands per million per year”. Much has been said about the value of biodiversity and the fact that the rate of loss is increasing. Although there are several causes of biodiversity loss, a

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113 Timothy R Tomlinson & Olayiwola Akerele, eds, Medicinal Plants: Their Role in Health and Biodiversity (University of Pennsylvania Press, 1998) at 3 see also preface. ; Mouhssen Lahlou, “The Success of Natural Products in Drug Discovery” (2013) 4 Pharmacol Pharm 17 at 18 The article states that close to 40% of modern drugs or compounds are derived directly or indirectly from natural substances such as plants.
115 Ibid Article 2, para 1.
116 Ibid Preamble, para 2.
117 Ebermann, supra note 110 at 26.
118 For example, see Tomlinson & Akerele, supra note 113; Luis Maffi, “Linguistic and biological diversity: The inextricable link” (2005) 29 Annu Rev Anthropol 599 (discussing the alarming rate of cultural and linguistic loss).
considerable portion of loss has been linked to human causes.\textsuperscript{119} Scientists have termed this loss of biodiversity by human causes “the sixth great mass killing of species in earth history” through past and present human activity.\textsuperscript{120}

Several governments and other entities have been working to curb the rate of biodiversity loss domestically and internationally. While much has been done domestically in numerous countries, the global nature of the problem has brought together most every country in the world. In 1988, the United Nations Environmental Program (UNEP) set up an Ad Hoc Working Group of Experts on Biological Diversity “to explore the need for an international convention on biological diversity.”\textsuperscript{121} The work of the committee resulted in the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. The Convention on Biodiversity and two instruments that emanated from the convention’s framework are essential to domestic and international discussions on the protection of biodiversity and TK.

The 1993 Convention on Biological Diversity (CBD), which now has 194 member countries, was negotiated and signed as a result of the common concerns about the alarming trend of biodiversity loss. The Convention is a high watermark signaling a shift in approach from considering biodiversity a ‘common heritage of mankind’ to one that considers biodiversity a ‘common concern of mankind’ over which countries have ownership.\textsuperscript{122} This change in approach is implied in the affirmation of the Convention “states have sovereign rights over their own biological resources”\textsuperscript{123} and in the provisions calling for the sharing of benefits arising from the use of TK.

\textsuperscript{120} Sharon L Spray & Karen L McGlothlin, eds, \textit{Loss of Biodiversity} (Lanham: Rowman & Littlefield,\textcopyright 2003., 2003) at 3–4 (Discussing the ways in which human activity has resulted in mass killings which is defined as the destruction of more than 50% of a species).
\textsuperscript{123} \textit{The Convention on Biological Diversity, supra} note 114 Preamble, para4.
and genetic resources.\textsuperscript{124} The CBD is “the most authoritative international instrument yet that recognizes … traditional knowledge.”\textsuperscript{125}

Although the focus of the CBD is on the conservation of biodiversity, traditional knowledge is considered to be an inherent part of such conservation. The CBD repeatedly refers to `traditional knowledge associated with genetic resources (biological resources).’ Although on the face of it this phrase might seem limiting, given the broad definition of `biological resources’ and `genetic resources’ it covers almost all TK.\textsuperscript{126} In addition to this initial interest in `traditional knowledge relevant to the conservation of biodiversity’ the follow-up instruments enacted to enforce the CBD and the post-CBD deliberations increasingly addressed TK protection. As highlighted in the following section and in Chapter Five, this reflects the increasing attention that TK received globally following the signing of the CBD.\textsuperscript{127}

Several CBD provisions have implications for TK protection. For instance, paragraph 12 of the preamble recognizes that indigenous peoples and local communities have close ties to biodiversity and member countries are interested in having a benefit sharing mechanism when TK from such communities is used by outsiders.\textsuperscript{128} This preambular statement does not have any clear requirement for TK protection. It merely highlights that member countries desire the sharing of benefits arising out of the use of TK. Article 8 (j) has a bit more substance in this regard. It states that member countries:

\begin{quotation}
\ldots shall, as far as possible and as appropriate:
\end{quotation}

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\textsuperscript{124} \textit{Ibid} Preamble, para 12.
\textsuperscript{125} Oguamanam, \textit{supra} note 8 at 5.
\textsuperscript{126} Article 2 of the convention defines the terms as follows: “'Biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity; “Genetic resources” means genetic material of actual or potential value." \textit{The Convention on Biological Diversity, supra} note 109, Article 2.
\textsuperscript{127} The history of international developments relevant for TK protection, including discussions at the Convention on Biodiversity, the World Trade Organization and World Intellectual Property Organization is addressed under Chapter Five.
\textsuperscript{128} \textit{The Convention on Biological Diversity, supra} note 114 Preamble, para 12.
Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.\textsuperscript{129} [Emphasis mine]

Although this provision is more detailed than the preambular statement, it is still general and highly qualified. As a result, its enforcement has been ineffective. Although the Convention reaffirmed state sovereign rights over biological resources, it does not provide the specifics of such rights. For instance, the convention under Article 11 calls on signatories to take measures that encourage the “conservation and sustainable use of components of biodiversity.” As such, it is only a general framework convention in need of additional instruments in order to be effective.

The Bonn Guideline\textsuperscript{130} and the Nagoya Protocol\textsuperscript{131} are key instruments in making the CBD clearer. The Bonn guideline is a voluntary instrument focused on regulating access to genetic resources in general. Although the guideline does not go as far as some have hoped, it is an essential international instrument highlighting the close relationship between genetic resources\textsuperscript{132} and traditional knowledge. The deliberations post-Bonn led to the Nagoya protocol.

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\textsuperscript{129} \textit{Ibid} Article 8 (j).
\textsuperscript{130} Secretariat of the Convention on Biological Diversity, \textit{The Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization, Conference of the Parties to the Convention on Biological Diversity - COP 6 Decision VI/24} (Secretariat of the Convention on Biological Diversity, 2002).
\textsuperscript{131} \textit{The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity}, 12 October 2014 [\textit{The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity}].
\textsuperscript{132} The Bonn guidelines adopt the same definition of ‘genetic resources’ that is adopted under article 2 of the CBD. In the instruments, “Genetic resources” means genetic material of actual or potential value.”
\end{flushleft}
The Nagoya Protocol was negotiated for six years under the framework of the CBD and was adopted in 2010. The purpose of the protocol is to provide legal certainty and clarity in implementing the CBD’s third objective – access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. The protocol is binding on countries that ratify it and requires that there be fair and equitable benefit sharing between users and providers. In the context of TK, the protocol requires that the Prior Informed Consent (PIC) of indigenous and local communities be sought and that there be mutual agreements on access and benefit sharing. As the latest international attempt at protecting genetic resources and TK, the success of the protocol will have considerable impact on realizing the potential TK holds. Since most of the user countries have not yet ratified the protocol, there is much to be done before the objectives of the protocol will be met.

The brief discussion of the CBD, the Bonn guideline and the Nagoya protocol provided above is meant to highlight the relationship between biodiversity and TK and to introduce international developments related to this relationship. More detailed discussion of the proposals for the protection of TK under international treaties is provided in Chapter Five.

In parallel with the international discussions on biodiversity, the World Health Organization (WHO) has been studying traditional medicine. The focus of the organization is on finding common ground for both critics and advocates of the use of traditional medicinal knowledge. The section below discusses recent approaches to integrating traditional and modern medical systems.

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133 The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity, supra note 131 Introduction.
134 Fifty seven countries had ratified the protocol by October, 2014 and therefore it would be binding on such countries. It is expected that more countries who are already members will ratify the protocol.
136 See Chapter Five, Section 3.2
1.8 Traditional Medicinal Knowledge and Integrated Medical Systems

There is a recent trend in the relevant literature recognizing pluralistic medical systems as the best way to addressing the needs of citizens.\textsuperscript{137} What is meant by pluralistic medical systems is the recognition, promotion and use of both Western and traditional medicine. Here although the term ‘Western medicine’ is used (within this thesis and with the dominant portion of relevant publications) various other terms are used to define the same or similar concepts. Alternative terms used include ‘biomedicine,’ ‘modern medicine,’ ‘allopathic medicine,’ or ‘evidence-based medicine.’\textsuperscript{138}

The WHO’s report - ‘Traditional Medicine Strategies (2002-2005)’ - is one of the few international documents that officially recognizes the value of traditional medicine. The WHO dedicates a section of the document to balancing the extreme positions it calls ‘uncritical enthusiasm’ and ‘uninformed skepticism’ about the use of TM.\textsuperscript{139} It attempts to reconcile these two extreme positions with what it calls ‘rational use.’\textsuperscript{140} Here rational use means the “… qualification and licensing of providers; proper use of products of assured quality; good communication between [TMK] providers, allopathic practitioners and patients; and provision of scientific information and guidance for the public.”\textsuperscript{141} Provided that the above discussed undertakings are conducted in an effective way, there is reason for some ‘critical enthusiasm’ about benefits of TM for patients in both developing and developed countries.

There is substantial empirical evidence that could help in swaying the position of ‘uninformed skeptics’ about the potential of TM and the need for its protection. Research shows most people

\textsuperscript{137} World Health Organization, \textit{supra} note 48 at 5 & 7.
\textsuperscript{138} Oguamanam, \textit{supra} note 8 at 34; World Health Organization, \textit{supra} note 48 at 1.
\textsuperscript{139} World Health Organization, \textit{supra} note 48 at 2.
\textsuperscript{140} \textit{Ibid} at 26–29, & 48.
\textsuperscript{141} \textit{Ibid} at 4.
in Asia and Africa use TM more than Western medicine. This could be explained as a result of the lack of accessible Western medicine in those areas. However, what is surprising is that TM is widely used even in countries where Western medicine is readily available. For example, “[i]n Japan, 60-70% of allopathic doctors prescribe Kampo medicines for their patients.” Various reports studied by the WHO show that “the percentage of the population that has used CAM [Complimentary Alternative Medicine] is 46% in Australia, 49% in France and 70% in Canada.” (Internal citations omitted) Reports from other developed countries also show significant national expenditure on TM.

However, it should also be noted that the use of alternative medicine has been highly controversial. There have been criticisms that alternative medicine lacks evidence of efficacy and that in some instances potentially detrimental medical practices are undertaken. Despite such criticism, the use of alternative medical systems by doctors trained in Western medical system shows encouraging interaction between the two. Such interaction is not limited to professionals. In fact, most major pharmaceutical companies have dedicated significant resources to seek potential drugs through the exploration of TMK. Some of these endeavors have resulted in

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142 The WHO reports that close to 80% of people in Africa use TM. Ibid at 9.
143 Ibid at 11.
144 Ibid.
145 US ($27 billion), Malaysia ($500 million – as compared to $300 million on Western medicine), Australia ($800 million), UK (£500 million); See Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Workshop report (New Delhi and Geneva: World Health Organization, 2001) at 6 Section 2.1.
146 For instance, see Megan Griffith-Greene, Vaccine Alternatives Offered by Homeopaths “Irresponsible” (2014).
147 Oguamanam, supra note 8 at 6.
successful groundbreaking drugs.\textsuperscript{148} Examples of TMK used to extract useful compounds and drugs including aspirin, digitoxin, morphine, quinine, and pilocarpine.\textsuperscript{149}

The above discussion of the value of TMK is not provided with the intention of engaging debate about the efficacy of TMK itself. The thesis put forth in this dissertation does not rely on the efficacy of TMK independent of Western medicine. Since the focus of this dissertation is to examine the regulation of the use of TMK in bioprospecting projects, it suffices to show that TMK has some value as an input in the drug discovery process. The purpose of this section is therefore to show the widespread use of TMK in both developing and developed countries. This fact coupled with empirical evidence showing that 80% of approved drugs have the same or similar use as in TMK, can make a case for the need to facilitate and regulate the use of TMK in bioprospecting projects. If the use of TMK is regulated in an efficient manner, the drug discovery process may become less time consuming and less costly. As the WHO noted in its strategy document, “[t]he economic benefits that can accrue from large-scale application of [TMK] can be substantial. Questions about how these benefits can best be shared between innovators and the holders of TM knowledge have not yet been resolved though.”\textsuperscript{150}

The potential beneficiaries of TMK use can be grouped into five clusters, taking into consideration both independent uses of TMK and TMK uses in modern medicine. These beneficiaries include: users of traditional medicine in its independent form; members of the knowledge holding communities; those who use TMK in bioprospecting projects; patients that benefit from modern medicine developed through the use of TMK; and the general public that benefits from the continued conservation of TMK and biodiversity. Some TMK protection could benefit all five

\textsuperscript{148} For example, five of the most famous attempts by pharmaceutical companies to produce drugs based on TMK have been discussed by professor Abena Dove Osseo-Asare. See generally, Osseo-Asare, \textit{supra} note 1; The use of Argan oil is another recent example in which traditional knowledge is used to produce a successful product. BBC, \textit{Argan Oil Helps Moroccan Women Become Breadwinners}; For an example of a traditional medicinal knowledge from the Western world which has been found to be useful in modern drug development, see Christina Lee, “AncientBiotics - a medieval remedy for modern day superbugs?”, (March 2015), online: <http://www.nottingham.ac.uk/news/pressreleases/2015/march/ancientbiotics---a-medieval-remedy-for-modern-day-superbugs.aspx>.


\textsuperscript{150} World Health Organization, \textit{supra} note 48 at 4.
groups or only a few of them. Since the focus of this dissertation is on the use of TMK in modern medicine, the direct beneficiaries of the framework of protection discussed throughout the dissertation will be knowledge holder communities; those who use TMK in bioprospecting projects; patients that benefit from modern medicine developed through the use of TMK; and the general public.

Because of the importance that TMK plays in the lives of so many people, discussion of the rationales for protection have taken place within institutions and academia in recent years. Such discussions involve a wide variety of arguments involving economic, practical and moral rationales. Because of the diversity of the proposed arguments, a detailed discussion of each rationale is beyond the scope of this dissertation. However, a brief analysis is provided in the sections that follow.

1.9 Modes of Protection for Traditional Knowledge

The term ‘protection for TK’ may have different connotations depending on the context. For instance, it might mean “preserving it” because its existence has inherent value to knowledge providers and to the world; or it might mean “promoting it” in order to increase the number of users worldwide currently and in the future. More controversially, it might mean “controlling its use” by giving knowledge holders power to decide how it is used, or it might mean establishing a benefit sharing scheme between users and providers. Therefore, discussions of TK protection will depend on what mode of protection is being considered. There are two general groupings of the modes of TK protection, which are discussed below.

152 Ibid.
Defensive protection has been defined as the attempt to stop outsiders from claiming intellectual property rights over TK.\textsuperscript{153} There have been several instances of patent applicants using TK to claim patent rights without the knowledge and consent of the TK holding community. These attempts are popularly labeled ‘biopiracy.’ ‘Biopiracy’ (short for biological piracy) is a term used to describe situations in which patent rights (or other intellectual property rights) are granted over an invention or an expression that is based on a TK (broadly defined) without compensating the source community or country.\textsuperscript{154} This includes situations where there has been a commercial use of the invention or expression for which an IP right has not been applied.\textsuperscript{155} What amounts to biopiracy is a controversial issue and it will be part of the discussion in this dissertation. However, at least, uses of TK through misleading contracts with TK holding communities, or in violation of the laws of the source jurisdiction or receiving patent rights over non-innovative inventions should be considered an action of biopiracy.

One of the best known cases of biopiracy is that of the Neem tree. More than 40 US patents (and globally 150 patents) have been linked to the Neem tree.\textsuperscript{156} At least two patents that have been challenged were licensed to W.R. Grace Co. and claimed a “[s]torage stable pesticide compositions comprising neem seed extracts” and the process of producing such extract.\textsuperscript{157} The Neem tree had been used in India in numerous ways including as a medicine, toothbrush, and contraceptive. Similar to its traditional use, the use of the compound claimed in the patent is as a fungicide. The granting of the patent in the U.S. and Europe, among other jurisdictions, caused uproar in the India because communities have been using the compounds of the tree to the very

\textsuperscript{153} Graham Dutfield, \textit{Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation} (International Centre for Trade and Sustainable Development (ICTSD), 2003) at 27.
\textsuperscript{155} \textit{Ibid} at 13.
\textsuperscript{156} Graham Dutfield, \textit{Intellectual property, biogenetic resources, and traditional knowledge} (Sterling, VA: Earthscan, 2004) at 53.
same purpose for thousands of years. The patent by the European Patent Office was revoked as a result of a challenge brought before a court in Munich.

Since defensive protection utilizes already existing laws including IP laws, some countries and international organizations have already started practicing it. Most notably, India has established a Traditional Knowledge Digital Library (TKDL) which provides a searchable database of recorded TK. The library was established after acts of biopiracy involving Indian TK were reported. In the time between its first use in a patent proceeding in July 2009 and October 6, 2014, it was included in at least 201 patent applications, resulting in rejection of applications, revocation of patents rights, amendments of claim(s) or withdrawals by applicants. Similar defensive attempts have been adopted in China, South Korea and South Africa. WIPO’s Creative Heritage project also plays a part in documenting TK and providing training so that culture is not misappropriated by outsiders. A more detailed discussion of the TKDL and other TK

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161 For an up-to-date involvement of the database in patent prosecution, revocation or amendment, See “Traditional Knowledge Digital Library: Major Milestones”, online: <http://www.tkdl.res.in/tkdl/langdefault/common/milestones.asp?GL=Eng>.
162 For a discussion of the TK databases in India, China, South Korea, South Africa and Venezuela see Section 5.1 in Chapter Two.
163 The World Intellectual Property Organization defines the term ‘misappropriation’ as follows: "In the field of intellectual property, Black’s Law Dictionary defines ‘misappropriation’ as “the common-law tort of using the noncopyrightable information or ideas that an organization collects and disseminates for a profit to compete unfairly against that organization, or copying a work whose creator has not yet claimed or been granted exclusive rights in the work. […] The elements of misappropriation are: (1) the plaintiff must have invested time, money, or effort to extract the information, (2) the defendant must have taken the information with no similar investment, and (3) the plaintiff must have suffered a competitive injury because of the taking.” The tort of misappropriation is part of unfair competition law in the common law system. Misappropriation thus entails the wrongful or dishonest use or borrowing of someone’s property, and is often used to found action in cases where no property right as such has been infringed. Misappropriation may refer to wrongful borrowing or to the fraudulent appropriation of funds or property entrusted to someone’s care but actually owned by someone else." World Intellectual Property Organization, “Glossary: Key terms related to intellectual property and genetic resources, traditional knowledge and traditional cultural expressions”, online: <http://www.wipo.int/tk/en/resources/glossary.html#38>.
databases will be provided in Chapter Three. Here, it helps to note that misappropriation is not a clearly defined concept and is an area of debate with TK protection. Such debate is discussed in the section on distributive justice below.  

The other mode of protection - positive protection - aims at giving TK holders the right to control use of TK by non-indigenous actors. Most of the positive protection of TK may be seen as analogous to the positive rights in patents, copyrights, trademarks and trade secrets. The positive mode of protection for TK is more contentious than the defensive one. Although, because of the global political divide discussed above, positive protection of TK may not be realized soon, the draft article prepared by WIPO on the protection of TK includes positive protection. On the other hand some countries have laws protecting TK and providing for access and benefit-sharing regimes.

While defensive protection is less contentious, it misses the potential offered by positive protection. Under a positive protection, knowledge holder communities may be more willing to share their knowledge with outsiders because of the level of control they have over what happens to their knowledge once it is shared. As a result, knowledge holder communities and users could collaborate to use TK in the production of new products and services. Such collaboration could result in new fields of research and development. If legal protection is limited to defensive protection, knowledge holders may still distrust outsiders and be unwilling to share their TK. This dissertation advocates for the establishment of positive protection because of the considerable potential that such protection offers stakeholders and the general public.

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165 See Section 2.1.1 on Distributive Justice below

2 Justification for the Protection of Traditional Knowledge

The protection of TK has been controversial since it assumed prominence in the international arena in the early 1990s. Because TK is at times generally used to encompass a wide variety of subject matter, including genetic resources and traditional cultural expressions, the justifications and modes of protection vary depending on context. The definition adopted in this thesis is a narrow one and refers to the know-how, skills, and practices of indigenous and local communities. In this context, the arguments for the protection of TK can be placed into three groups: equity-based justification, property rights claims, and consequentialist claims. There is no universally agreed upon justification for the protection of TK. However, international negotiations take place despite this lack of a coherent theory.

Below is an outline of the three major groupings of justification. It should be noted at the outset that the below discussions are not endorsements of the core arguments. The sections are provided in order to give a general picture of the diverse perspectives scholars have taken on the protection of TK. While some of the arguments made in the theories put forth hold sway, there are two main criticisms that this dissertation posits against many of the perspectives.

The first criticism is the failure of the existing literature to focus on minimum consensus on the topic: the need to encourage the codification of TK. While some arguments made by scholars in the area have highlighted the need for documenting TK, they have done so only in passing. There does not seem to be a scholar who builds on the consensus on the need to codify TK as an organizing principle for the protection of TK. Second, the literature on TK protection is dominated

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168 Other authors have classified the justifications for protection into different groups such as property justifications, incentive justifications, distributive justice and human rights. See generally Munzer & Raustiala, supra note 18; See also Carlos Maria Correa, Traditional Knowledge and Intellectual Property: Issues and options surrounding the protection of traditional knowledge - A discussion paper (Quaker United Nations Office, 2001).
by equity, distributive justice, and human rights arguments. There is only limited scholarship using economic efficiency as a core rationale for the need to protect TK. Adopting such an argument is bound to bring new stakeholders on board whose priorities are economic efficiency and development. Many commentators that focus on equity-based rationales tend to be antagonistic to policies couched in the promotion of economic efficiency and vice versa. This dissertation can help bring these perspectives together by showing that these seemingly conflicting perspectives can coexist. The core thesis provided in this dissertation is discussed further at the end of this chapter and throughout the succeeding chapters.

2.1 Equity Based Justifications

The equity-based arguments that scholars make to justify the protection of TK may be further grouped into distributive justice, human rights and other equity-based justifications. While there are theories spanning all three groups, a grouping of such theories will help in providing an organized commentary. The below sections are thus grouped here partly for convenience.

2.1.1 Distributive Justice

Given the history of relationships between Western societies on the one hand and indigenous and local communities on the other, arguments based on distributive justice have frequently been proposed. The distributive justice argument is reflected in three different lines of highly interrelated thought: equity, natural (moral) rights, and unjust enrichment.

With regard to equity, scholars argue that TK holders have for generations predominantly created and conserved plant varieties, traditional medicines and healing practices, traditional cultural expressions, etc. without receiving recognition. This injustice is further exacerbated by the fact that formal protection mechanisms protect improvements and innovations that utilize TK while

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169 Correa, supra note 168 at 6; Oguamanam, supra note 8 at 28.
failing to recognize the rights of TK holders. The effect of such a system is that TK holders who are the basis of innovation are not only excluded from any kind of benefit but are charged in order to use improvements and innovations based on such knowledge. Therefore, the rationale for TK protection under this reasoning is to undo this inequity resulting from the lack of a framework that recognizes and protects centuries of contributions made by TK holders.

Similarly, it has been argued that TK holders have *moral rights* over the knowledge they produced and conserved for centuries. Proponents of this justification for TK protection adopt the moral right of creators from continental Europe’s legal systems and the Bern convention, which mostly focus on subject matters of copyright. Munzer and Raustiala, although noting that moral rights are contested, agree that such justification should give indigenous people two sets of rights as conceived by Wesley Hohfeld: first is a “narrow liberty-right and/or claim-right would be disclosure (*divulgation*): to make an item of their TK known to the world … but to retain the power to keep that item from being used in any way by others” followed by the "claim-right and power … to prevent the attribution of an item of TK to any person or group other than the indigenous community that generated the item." Here, it should be noted that, although the narrow liberty-right that knowledge holder communities have to ‘keep the item from being used by others’ seems a strong right, it is in fact limited. This is because Munzer and Raustiala are here referring to keeping the knowledge of the existence of the TK public, but not to divulge the substance of the knowledge publicly, thereby keeping it secret. Here, the effect of such a narrow liberty-right would be to put conditions on outsiders that deny access to TK deemed secret by the community. Munzer and Raustiala add that since the justification for moral rights relates to ‘personhood’ of the creator, some TK might be more justified than others. In this sense, folklore

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173 Correa, *supra* note 168 at 8; Munzer & Raustiala, *supra* note 19 at 68–73 Because moral rights mostly focus on copyrights (with limited applications in patents and trademarks, the argument becomes limited.
174 Munzer & Raustiala, *supra* note 19 at 73.
175 Ibid at 70.
seems to be more attached to indigenous people than other forms of TK, and may, therefore, be more justified under moral rights. Although moral rights may justify protection of TK to a limited extent, the content of the rights is still debatable.

Lastly, under the distributive justice group, it is argue that TK protection is needed to stop unjust enrichment and misappropriation. Users who tap into TK to develop products and services usually do not share the benefits that they receive with TK providers. Major biopiracy cases arise when the value of TK is high and the firm or individual using it is unwilling to share any of the benefits arising from it. Since the TK that is used as input increases the benefits to users, their refusal to share the benefits raises unjust enrichment and misappropriation claims. Such claims might succeed in appealing to morality and a sense of justice but legal intervention is not always justified in such cases. There are situations in which unjust enrichment takes place but because of other policy reasons the law does not regulate them. Yet, the fact that the law refuses to regulate other areas of social activity cannot be used as a rationale for arguing that it should act the same way with TK. If there are sufficient reasons for intervention, a carefully crafted system of protection may become necessary.

Patent laws of some jurisdictions which disregard non-published material from other jurisdictions in their analysis of novelty have been criticized for aiding in the unjust enrichment of patent applicants. If prior knowledge of the ‘invention’ is found only in oral traditions or in

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176 Ibid.
177 The uproar that results when companies applied for patent rights over genetic resources and traditional knowledge used by indigenous and local communities is caused by, among other things, the refusal to share benefits. The most famous cases of biopiracy include the neem tree, basmati rice, the hoodie plant, turmeric, the Rosie periwinkle plant and the ayahuasca plant. As highlighted at the beginning of this chapter, in the case of the hoodie plant, the user of the TK agreed to share benefits only after substantial public pressure forced it to do so. For a detailed discussion of famous biopiracy cases from the African continent including the Hoodia and Rosy Periwinkle case, see generally Osseo-Asare, supra note 1.
178 For example, Munzer and Raustiala quote a conversation from the Sopranos series in which two Italian-American characters in a Star bucks shop discuss it is unfair that the coffee chain benefits from the fame that coffee has gained through Italian culture. Munzer & Raustiala, supra note 19 at 77–78.
179 The US patent law before the enactment of the America Invents Act (AIA) signed into law on 16 September, 2011 did not recognize unpublished materials from other jurisdictions in its novelty analysis. However, one of the changes brought about through the AIA is the recognition of any publicly available knowledge regardless of jurisdiction. The current version of 35 U.S.C. 102 (a) (1) states that a patent should be granted unless: “...the
undocumented practices these jurisdictions will not take such undocumented knowledge into consideration when making a novelty (newness) assessments. The result may be that a non-innovative invention based on an undocumented prior knowledge could pass the novelty (newness) test for patentability. A considerable part of TK is oral in nature and some patent systems do not consider such knowledge in patent examinations. The effect of limiting prior art recognition to documented knowledge may therefore result in the patenting of TK that has been held and transferred by communities orally. However, although such criticism may be valid, evidentiary accessibility concerns may support the requirement for some sort of written evidence to show the existence of prior art. Patent examiners in a distant jurisdiction cannot be required to know of the existence of a TK prior art if it is not made accessible by way of written publication.

2.1.2 Human Rights

Human rights are a major part of the discussion on the protection of TK. The Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) have provisions that some scholars have argued will cover claims of TK holders. It has been argued that the prohibition against discrimination under Article 7 of the UDHR and the right to self-determination under Article 1 could be used to claim

claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” The pre-AIA version of this provision stated that a patent should be granted unless “A person shall be entitled to a patent unless "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.” Horton, supra note 84 at 15 & 23.

180 McManis & Teran, supra note 83 at 22.
181 The Universal Declaration of Human Rights, 10 December 1948 [The Universal Declaration of Human Rights] Article 27 states that: “(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”
182 International Covenant on Economic, Social and Cultural Rights, 16 December 1966 [International Covenant on Economic, Social and Cultural Rights] Article 15 (1, b, c) states that: "1. The States Parties to the present Covenant recognize the right of everyone: ... (b) To enjoy the benefits of scientific progress and its applications; (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
equality of protection in traditional and formal knowledge.\textsuperscript{184} On the producers’ side, Article 15.1 (c) of the ICESCR recognizes the “right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”\textsuperscript{185} The justification for the protection of TK here would be that since TK holders produced and conserved TK for generations, they have human rights to benefit from it.

However, attempting to use the human rights route to justify the protection of TK brings challenges. As John Mugabe rightly argues, human rights literature focuses on individual rights, which might not cover TK, which is almost always a claim for communal right.\textsuperscript{186} For instance, the above quoted provision from the ICESCR is focused on an individual ‘author’ and therefore might not be readily applicable to the communal authorship dominant in knowledge holding communities. Until the issue has been resolved authoritatively, the question of the applicability of such provisions to knowledge holder communities remains arguably. Furthermore, the same Article seems to recognize the “right to benefit from protection” if such protection is already recognized in the domestic law of the relevant jurisdiction. It does not seem to be requiring that protection for intellectual production be created by every member country. Therefore Article 15 (c) of the ICESCR seems to be limiting the applicability of the provisions to jurisdictions that already protect TK. Mugabe further notes that since the obligation to fulfill human rights usually rests on states, and since various states have already declined to recognize TK, using a human rights approach to justify protection will be challenging.\textsuperscript{187}

Along the same lines, conventions that deal with indigenous people have covered the protection of TK. Mugabe argues that the Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries should be read to include the protection of TK.\textsuperscript{188} However, the convention has been criticized for lack of

\textsuperscript{184} Mugabe, \textit{supra} note 10 at 111.
\textsuperscript{185} \textit{International Covenant on Economic, Social and Cultural Rights}, \textit{supra} note 182 Article. 15 (c); The text under the article is similar to the wording under article 27 of the UDHR.
\textsuperscript{186} Mugabe, \textit{supra} note 10 at 112.
\textsuperscript{187} \textit{Ibid}.
\textsuperscript{188} \textit{Ibid} at 113.
specificity and as such might not meet the needs of TK holders. Perhaps the strongest international declaration of IP rights for TK holders comes from the United Nations Declaration on the Right of Indigenous Peoples (UNDRIP), which declares that indigenous peoples “… have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.”

This is a general, unenforceable statement and it does not attempt to engage with the nuances that exist in the protection of TK. The UNDRIP’s recognition of the right of knowledge holding communities to protect their intellectual property might arguably be a call for a property right in TK, given the dominance of property rights in conventional intellectual property laws. But, since there are alternative intellectual property laws in effect in many jurisdictions, it is not clear what legal framework the UNDRIP is calling for.

Read independently, the statement serves only as a general declaration of agreement on the need to protect the intellectual property in TK. In this sense, it is in stark contrast with the controversial draft instrument of the World Intellectual Property Organization on the protection of TK. While the draft instrument attempts to specify the details of TK protection, there seems to be a gap in negotiating positions on almost all of its provisions. The draft instrument will be discussed in detail in Chapter Five.

2.1.3 Other Equity-Based Justifications

In addition to the abovementioned main equity-based justifications for the protection of TK, some scholars have proposed justifications that may only apply to some elements within TK. For example, some scholars have equated the misuse of indigenous signs and designs in clothing, artifacts and other products with trademark and copyright infringement. The core concepts of

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189 Ibid.
191 A blog hosted by a multi-year international research project IPinCH has documented many 'appropriations (?)' of the cultural expressions and knowledge of indigenous peoples on a monthly basis. See “Appropriations (?) of the Month” in “Blog | Intellectual Property Issues in Cultural Heritage”, online: <http://www.sfu.ca/ipinch/outputs/blog>; The recent advertisement by Urban Outfitters of a clothing labeled as
trademark law, such as infringement, passing-off, and dilution, have been used in discussions of TK protection. As discussed above, some argue that the continental European conception of moral rights of authors under copyrights could be expanded to recognize collective moral rights of TK holders.

While these justifications may rightly apply to some elements of TK, there are challenges in applying them to justify the holistic protection of TK. The challenges mainly stem from the fact that the rationales used to justify the application of these rules to TK only apply to part of it. For instance, the underlying rationale for moral rights in many jurisdictions may not easily justify the granting of a communal moral right over TK. Moral rights include the right to receive proper attribution and the right to keep the integrity of a work and these rights rely heavily “on the connection between an author and her creation.” They are mainly focused on the “personal and reputational” value of copyrighted works. Since the producers of TK are usually unknown and may even change over time, granting moral rights to the living generation of knowledge holder communities may not fit well with the underlining rationale for the granting of moral rights. Therefore, it is only in cases where there is a clear connection between the author of a certain cultural expression and the expression itself that moral rights could apply. Moral rights would also be hard to apply for know-how (as opposed to expressions) and, so, TK as defined in this dissertation may not fit well with moral rights.

2.2 Property Rights and Consequentialist Justifications

Similar to equity-based justifications, the utilitarian arguments that scholars make for the protection of TK have diverse lines of thought. It is possible to group such lines of thought into

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“Vintage Linen from the 90s” caused an uproar among some as it closely resembles the Ethiopian/Eritrean cultural dresses. Concerned individuals argued that the act is similar to passing-off or trademark infringement. Aljazeera, *When Traditions Become Trends* (2013).


194 Ibid.
two groups: property rights arguments and consequentialist justifications. These are claims that are based on property rights in the strict sense of the term and those that are incentives based. A brief discussion of each group is provided below. It should be noted here that property rights arguments have been featured in the earlier section and both groups of claims discussed here could also be labelled as property rights claims at their core. The categorization is expected to facilitate discussion and is not meant as a strict clustering of the arguments put forth by scholars.

2.2.1 Property Rights Arguments

While some proponents of the protection of TK have borrowed from standard principles of property law such as “dessert based on labor”, firstness and stability\(^\text{195}\) others have expanded the usual ‘ownership’ theory of property and adopted a ‘stewardship’ justification for rights in ‘cultural property’.\(^\text{196}\) Critics of using property rights to justify the protection of TK have argued that only very limited protection for TK (defensive protection and limited type of positive protection) is warranted under core conceptions of property rights.\(^\text{197}\)

The ‘fruit of labor’ justification for property rights, a Lockean concept, rests on grounds of merit and posits that whoever labors to create, develop and improve something should be given rights related to it. The nature of rights depends on the amount of labor applied, meaning the more labor expended to produce a product the stronger the right related to that product will be. Adopting this ‘dessert based on labor’ justification, advocates of TK protection argue that since traditional communities invest their time and energy in conserving and developing TK, they should be rewarded for their work through rights.\(^\text{198}\) This line of argument might be criticized for giving rights to the current generation of TK holders even though the TK was created by their ancestors.\(^\text{199}\) It may be true that current members of the community are engaged in incremental

\(^{195}\) Munzer & Raustiala, supra note 19.
\(^{196}\) Carpenter, Katyal & Riley, supra note 70.
\(^{197}\) Munzer & Raustiala, supra note 19 at 65.
\(^{198}\) Oguamanam, supra note 8.
\(^{199}\) Munzer & Raustiala, supra note 19 at 60.
improvement and innovation which should be supported by the provision of rights, but such an argument only entitles current generation of TK holders to the incremental knowledge they are responsible for producing, not the entire body of TK.  

The other property rights justification proposed by scholars for the protection of TK is the one based on firstness. It argues that Western societies take TK away from indigenous people who were there first, so it is just to give them rights over it. The argument for firstness is on a shaky ground under property rights and it becomes murkier still when used as justification for the protection of TK. The distantness of the current members of the indigenous community from the people who first developed a traditional method or created a folklore etc. may also be used to counter the ‘firstness’ justification. Since culture has continued to diffuse over time the ‘original’ members of the community that developed the knowledge may have borrowed it from another indigenous group, in which case the firstness justification becomes even weaker.

Stability is another rationale adopted from property rights literature to justify the protection of TK. The claim here is that since currently there is confusion related to the protection of TK, most TK holders and users are at a disadvantage in that they cannot refer to a clear body of law to guide their interactions. Thus, adopting clear laws that recognize rights in TK will help stabilize the confusion and also help in the transactions between TK holders and owners. Some documents adopted by the World Intellectual Property Organization (WIPO) have used arguments similar to ‘stability’ to ground the protection of TK. WIPO’s position is that the protection of TK through clear legislation would result in stability that would benefit all stakeholders and the society at

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200 Ibid at 64 & 73.
201 Ibid at 62–65.
202 Kwame Anthony Appiah, Cosmopolitanism: Ethics in a World of Strangers, 1st ed, Issues of Our Time (USA: W.W. Norton & Company, 2006). (Suggesting that cultures have always been mixing and so it is undesirable to attempt to keep them as pure as possible); for a shorter discussion of such claim, see Kwame Anthony Appiah, “The Case for Contamination”, N Y Times (1 January 2006), online: <http://www.nytimes.com/2006/01/01/magazine/01cosmopolitan.html>.
large.\textsuperscript{205} But clarity or stability alone should not be used to create substantive rights because clear rules stating that there are no rights in TK will have the same effect.\textsuperscript{206} While this may be true, a complete lack of protection can only exacerbate the already dire situation of TK loss. As discussed in the succeeding chapters, the ‘incentive to codify’ justification put forth and developed in this dissertation is based on the need to save TK from loss.

Kristen Carpenter, Sonia Katyal, and Angela Riley adopt a ‘stewardship’ theory to justify the protection of cultural property that includes intangibles.\textsuperscript{207} They claim that critics of TK protection incorrectly use a narrow conception of ‘property’ and they argue that instead of ‘ownership’ of property ‘stewardship’ of property, and instead of individual titles, ‘communal stewardship’ can be used to justify the protection of TK.\textsuperscript{208} Their argument is that since the conservation of cultural and intangible property is integral to the identity of indigenous peoples, the protection of TK is necessary to the identity and ‘peoplehood’ of these communities. The development of this ‘peoplehood’ argument is a communitarian extension of Margaret Jane Radin’s personhood theory\textsuperscript{209} of property.\textsuperscript{210} Under the theory developed by Carpenter and others, members of the indigenous group are seen as a ‘non-owner’ who have “… fiduciary obligations toward cultural resources” and the community as a whole has the right to control who utilizes their property (be it tangible or intangible) and how.\textsuperscript{211} While the stewardship theory might not fit into the Western legal system, it seems to fit the world views of indigenous people and local communities. However, applying such theory to TK would entail dramatic changes to the current IP regime which might make the proposal infeasible.\textsuperscript{212} The fear of such drastic disruption to the already complex and challenging framework of intellectual property law may make policy makers hesitant to adopt such a theory.

\textsuperscript{205} Ibid, para 34 - 36.
\textsuperscript{206} Munzer & Raustiala, supra note 19 at 67.
\textsuperscript{207} Carpenter, Katyal & Riley, supra note 70.
\textsuperscript{208} Ibid at 1097.
\textsuperscript{210} Carpenter, Katyal & Riley, supra note 70 at 1050.
\textsuperscript{211} Ibid at 1022.
\textsuperscript{212} Munzer & Raustiala, supra note 19 at 65 & 66.
2.2.2 Consequentialist Justifications

Part of the property rights argument for the protection of TK focuses on claims that the law will incentivize knowledge holders to do a variety of different things. It should be noted that although discussed separately from the property rights section, the below discussed consequentialist arguments fit under property rights theories in other areas.

These consequentialist arguments might further be divided into three lines of thought: incentive to invent, incentive to use or commercialize and incentive to conserve. A core justification for the creation of patent rights is the need to incentivize inventions, and proponents of TK protection adopt the very same justification. The argument is that protecting TK will encourage TK holders to invest in traditional innovations in the hope of getting the final reward of exclusive rights. Critics reject such a claim as they believe TK has already been created; however, they note that the claim could justify limited rights for the incremental innovation that current members of TK holders generate. Here it seems that the definitions of TK adopted by critics and proponents of TK are different. Most proponents of TK protection insist “the adjective ‘traditional’ qualifies the method of creating TK and not the knowledge itself.” Many scholars have argued that indigenous and local communities do engage in incremental and cumulative innovation. If the objective is to encourage TK holders to continue making these incremental and cumulative improvements, legal intervention may not be necessary. TK holder would continue to engage in such activities as they have in the past because they are necessary for their survival and quality of life. Additionally, these minor improvements could be protected by existing IP systems such as ‘petty patents’ (utility model certificates), if they fulfil the requirements for such systems. Petty patents (utility model certificates) are exclusive rights granted in some jurisdictions for minor

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213 For example, The US constitution gives Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Constitution of the United States of America, 1787 [Constitution of the United States of America] Article 1, para 8, sec. 8.
214 Munzer & Raustiala, supra note 19 at 73.
215 Carvalho, supra note 3 at 244.
216 Dutfield, supra note 59; Taubman, supra note 4.
improvements that may not meet the higher standard of inventive step (non-obviousness) found in patent laws.

Adopting a different perspective on incentives, some scholars see protection as facilitating the use and development (commercialization) of TK. This claim is also reflected in international treaties such as the Convention on Biodiversity (CBD). The claim is that if TK receives clear protection indigenous groups would trust the system and would be willing to share their knowledge which they would otherwise be hesitant to do.

This seems to be the strongest justification for the protection of TK. While other areas of TK protection are contentious, it is mostly widely accepted that the body of knowledge has been under-utilized. As explained in detail in Chapter Two, section 2.3, there is a trend in which knowledge holder communities and their governments are becoming increasingly restrictive in terms of access to TK. The core cause of such a protectionist trend seems to be the fact that these source communities do not have control over their TK once it has been shared with outsiders. The lack of benefit sharing, the absence of attribution, negative experiences from colonial times and offensive uses of TK have made knowledge holder communities become hesitant to share their knowledge. Such a protectionist trend is just one sign of the increasing under-utilization of TK. Additionally, the many successful and unsuccessful attempts of using TK; and the potential TK has for use in modern industries; and the frustration of users of TK resulting from the lack of legal certainty imply the existence of demand for TK and, in certain circumstances, their under-utilization.

218 Correa, supra note 168 at 8.
219 For example, five of the most famous attempts by pharmaceutical companies to produce drugs based on TMK have been discussed by professor Abena Dove Osseo-Asare. See generally, Osseo-Asare, supra note 1; The use of Argan oil is another recent example in which traditional knowledge is used to produce a successful product. BBC, Argan Oil Helps Moroccan Women Become Breadwinners BBC, supra note 157; For an example of a traditional medicinal knowledge from the Western world which has been found to be useful in modern drug development. See Lee, supra note 157.
220 Roberts, supra note 151 at 93.
The goal of legal intervention, to encourage knowledge holders to use and develop their knowledge, is therefore commendable. It is also feasible given successful instances of benefit sharing. Thus, the ‘incentive to codify’ justification outlined in the next chapter builds on such line of argument, as it is the most promising area for the creation of an organizing principle for TK protection.

However, while such a justification may make sense, there are risks of over or under investment. If a balance is not achieved between protection and dissemination, a system of TK protection could result in a reduction of access to TK, especially in the case of traditional medicine and genetic resources. Although empirical research on the implications of the over-protection of TK has not yet been conducted, literature from the law and economics of information goods shows that the social costs that result from restriction could, at times, be greater than the benefits. As discussed in Section 1.7, the full potential of TMK will only be realized in a collaborative environment within which knowledge holding communities and users work together. Achieving the balance that encourages collaboration should therefore be the policy objective. It should also be noted here that the incentive to commercialize justification is limited to knowledge that indigenous communities are willing to share and, as such, would not include things related to spiritual or religious activities.

The final consequentialist justification for the protection of TK is the incentive to conserve biodiversity, culture and lifestyle. With regard to biodiversity, the claim is that legal protection of traditional varieties would encourage farmers to continue preserving varieties that they would otherwise abandon for profit. The strategy here is to internalize the values that a certain

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221 For example, see the discussion surrounding the Honey Bee Network in India which has functioned for over 25 years on the basis of a pool of traditional knowledge innovation in Chapter Three, Section 5.1.1.

222 Correa, supra note 168 at 8; Munzer & Raustiala, supra note 19 at 74.

223 Correa, supra note 168 at 8.

224 See for instance, Michael A Heller & Rebecca S Eisenberg, “Can patents deter innovation? The anticommons in biomedical research” (1998) 280:5364 Science 698 (The authors identify the detrimental effects of over-protection through patents in the medical field.)

225 Munzer & Raustiala, supra note 19 at 74.

226 Correa, supra note 168 at 6.
biodiversity resource may have for the general public by granting rights to the communities that conserve the diversity of these genetic resources. The expected result is that the communities would consider their ability to extract increased profits from the protected resource and continue producing the resource, rather than move on to producing varieties that are more profitable for them.

Such a claim can be criticized simply by noting that farmers have been preserving varieties for years without the need for protection, so there is no need to grant them new incentives. However, because of the alarming rate at which biodiversity is being lost, the criticism becomes weaker. Additionally, conserving biodiversity requires investment and developing countries (holding close to 70% of the world’s biodiversity) cannot invest in it without adequate incentives.

The debate is also raised within developed countries which have significant indigenous populations where the claim is for domestic recognition and protection of TK. This is especially the case in the ‘enclave territories’ of developed countries.

The argument with regard to the preservation of cultural lifestyle claims that, because of globalization and resulting dominance of Western culture, other cultures faces high risk of extinction and, so, their protection through IPRs will help preserve them through commercialization and by attracting much-needed attention from current and future members of the community itself. However, the argument has faced criticism for being weak on several

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227 “Megadiversity” refers to the state of a locality in which it is host to a disproportionately high level of biological diversity. The uniqueness of a species to a certain country – endemism – is at the heart of the method used in determining which countries are megadiverse. Mega-diverse countries make up close to 70% of the biodiversity in the world, and the US and Australia are considered the only developed mega-diverse countries. See Biodiversity A-Z, Factsheet: Megadiverse Countries (United Nations Environmental Program and World Conservation Monitoring Center, 2014). See text accompanying note 226.


229 “Enclave territories” have been defined as countries in which colonial settlers did not withdraw and native people continue to live with settler communities. Oguamanam, supra note 8 at 3.

230 Some commentators claim that such risk of extinction is even worse than that faced by biodiversity. For example, see Correa, supra note 168 at 6–7.

231 International Institute for Environment and Development (IIED), supra note 34 at 5.
fronts, including, a lack of empirical support and a misinformed objective. Critics argue that cultures have been blending for ages, and the objective of cultural conservationists to keep cultures as authentic as they can be is, therefore, futile. Attempts to preserve culture should not impede cultural dynamism. Instead of being used as a tool for cultural conservation, intellectual property protection should focus on conserving knowledge through codification. The ‘incentive to codify’ justification outlined in the following chapter seeks to build on this line of thought.

These contentious justifications attempt to explain why TK, or at least some elements of it, should be protected. Even though scholars do not reflect consensus on the matter, there seems to be an understanding that TK should be protected at some level; be it defensively or positively. The question of what type of protection mechanism to adopt is one of the key points of contention in the protection of TK.

3 Statement of the Problem

The justifications discussed in the preceding sections have both strong and weak aspects to them. Thus, the discussion provided is not a full endorsement, nor is it a complete criticism. As discussed below, the justifications outlined earlier are limited in important ways. The ‘incentive to codify’ justification proposed in this dissertation seeks to fill these gaps. In a general sense, the above-discussed justifications face two core limitations.

The first such limitation is the failure of the rationales to create consensus. Each of the justifications put forth, with the exception of the ‘incentive to use and commercialize TK’, are contentious and may not garner sufficient support from stakeholders in the crafting of an effective TK protection mechanism. There are disagreements, for instance, on whether knowledge holder communities have a natural right or a human right over such knowledge; and on whether the use of such knowledge by outsiders should be characterised as unjust or wrong. The ‘incentive to

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232 See generally, Appiah, supra note 201 (Suggesting that cultures have always been mixing and so it is undesirable to attempt to keep them as pure as possible); for a shorter discussion of such claim, see Appiah, supra note 201.
codify’ argument avoids positioning the rationale on these contentious issues. By building on the most agreed upon issue about TK – that TK is faced with an alarming rate of loss and that a framework is needed to save it from such loss – the ‘incentive to codify’ argument may be able to encourage different actors to take part in establishing a feasible framework. In this way, the ‘incentive to codify’ argument will create a consensus, and it is, therefore, intended to be an organizing principle. As highlighted earlier, the loss of TK affects different groups of individuals, including knowledge holder communities, users, and the general public and, as a result, legal protection focused on saving TK from loss may garner support from various stakeholders.

Another core limitation related to the justifications discussed earlier is the dominance of non-economic rationales for the need to protect TK. As can be seen from the previous sections, the predominant arguments for TK protection are based on equity, distributive justice, and human rights arguments. Such arguments may not be able to draw support from knowledge users (such as firms) which may be better persuaded by arguments based on economic efficiency. At the international level, instrumentalist and economic arguments have the advantage of convincing developed countries of the north, where most users reside and which are susceptible to lobbying from such users, to agree to TK protection. By adopting an economic efficiency rationale for TK protection, the ‘incentive to codify’ justification is expected to bring on board new stakeholders interested in the continued access to and conservation of TK, while still meeting the needs of knowledge holder communities.

The use of an economic lens in this dissertation, however, does not necessitate the rejection of rationales based on other preferences. As stated earlier, many commentators that focus on equity-based rationales tend to be antagonistic to arguments based on the promotion of economic efficiency and vice versa. This dissertation can show that these seemingly conflicting perspectives can coexist. For instance, it may be both economically efficient and equitable to grant knowledge holder communities rights over TK. Thus, the focus on economic analysis can complement other rationales, so long as these rationales support the framework outlined in the chapters that follow.

This dissertation is not the first research to take an economic efficiency approach, however. While most scholars have cited economic efficiency as part of an argument, a few scholars have
used it as a core rationale for protecting TK.\textsuperscript{233} Some of the arguments discussed as part of the consequentialist framework in the previous sections focus on economic rationales. While these arguments analyze economic benefits and efficiencies involved in protecting TK, a focus on the public good nature of TK is limited, and an in-depth analysis of a focus on the need to codify and disclose TK is lacking. This dissertation thus builds on the limited literature to more fully develop an argument based on welfare economics for the need to encourage knowledge holder communities to codify and share their TK through the mechanism of legal protection.

While there are several perspectives even within utilitarian arguments advocating for TK protection, the single root of all such arguments is the fact that TK knowledge – like any other knowledge good – is a public good. While this does not automatically give rise to a need for government intervention, the failure of other channels of production, as evidenced by the continued and alarming rate of TK loss, means that intervention is urgently required. Therefore, the following chapter provides a public good conception of TK. It uses the public good analysis to show that government intervention is required in order to save the body of knowledge from oblivion. The third chapter will proceed to describe the ‘incentive to codify’ justification by analyzing the effect of legal protection in encouraging the codification of TK.

The other contribution of this dissertation will be in highlighting a worrying trend of increased restriction on access to TK and genetic resources. This trend labelled the ‘protectionist trend,’ is a resulted of the lack of legal protection for TK and genetic resources, and the frustration of source countries and communities with the slow progress in responding to their needs. This rising protectionist trend adds to the urgent need for the establishment of an effective system of TK protection soon.

4 Conclusion

This chapter has outlined many of the contentious features found in discussions of TK protection. The analysis begins by defining the scope of the term ‘traditional knowledge’. And varying definitions have been analyzed. A narrow definition has been adopted as the most fitting given the focus of this dissertation on the creation, use, and dissemination of knowledge, rather than on artistic and cultural expression. Thus, in this dissertation, TK is used to refer to the know-how, skills, practices, innovations and learnings of indigenous peoples and local communities. This definition is the one used by many scholars and international entities, including the World Intellectual Property Organization.

As stated in section 1.3 above, the emphasis of the thesis is on traditional medicinal knowledge. This is done first because a focus on TMK is expected to allow for a more detailed and coherent examination of the use of TMK in bioprospecting while avoiding the generalizations required for examining the larger phenomenon of TK. Second, TMK is selected as an area of focus because most of the leading debates in TK relate to the use of TMK in the bioprospecting industry. Third, most of the documentation of TK taking place in some jurisdictions relates to TMK.

The emphasis on TMK does not mean, however, that all discussion throughout this dissertation applies solely to TMK. Some of the general analysis may be applicable to other areas of TK. For instance, the discussions in the latter sections of the thesis on the public good analysis, and the impact of legal intervention for the documentation and disclosure of TK are all applicable to other types of TK. In these cases, reference is made to TK in general, as opposed to TMK. Where analysis is limited to TMK, reference is made only to TMK.

Currently, IP laws provide little protection for TK. In general terms, existing IP laws have a framework that does not fit well with the needs and expectations of knowledge holding communities. This has been linked to the historically Western origins of IP law which has a worldview different from that of most knowledge holding communities. More particularly, TK fails to meet two of the core requirements of patent laws: novelty (newness) and inventive step (non-obviousness). As such, patent laws are generally inappropriate as a form of TK protection.
That said, there may be a few scenarios where existing patent laws can protect TK, in which case, knowledge holder communities interested in making use of such laws could be encouraged to do so.

Knowledge holder communities rely heavily on biodiversity. Thus, the destruction of biodiversity has had a devastating impact on TK. As a result, international instruments whose main focus is biodiversity conservation have also addressed TK issues, albeit at a more general level. The provisions of the CBD and the Nagoya protocol have been discussed in this regard. In addition to these legal interventions to protect biodiversity resources, attempts have been made to address TK protection as a stand-alone issue. The work of the World Intellectual Property Organization is a key aspect of such attempt on the international stage and is discussed in detail in Chapter Five.

Two modes of protection have been identified in this chapter. Defensive protection seeks to stop non-indigenous people from claiming IP rights over TK. Most attempts at defensive protection are not contentious as they seek to better the existing IP system. The other mode of protection – positive protection – is more controversial. Positive protection of TK seeks to provide knowledge holding communities with the power to control how their knowledge is used by outsiders. The focus of this dissertation will be on this positive mode of protection.

As outlined in the preceding sections, scholars have advanced differing justifications for the need to protect TK. These justifications have been clustered into those based on equity, distributive justice, human rights, property rights and consequentialist theories. All of these theories have strong and weak aspects to them. The core limitation of most arguments discussed is an inability to create consensus in the field and bring key stakeholders in from the user side to want to establish an effective mechanism for TK protection. Arguments based on consequentialist concepts may generally have the potential to convince users such as biopharmaceutical firms and the governments of developed countries to buy into proposed frameworks. While a consequentialist justification of the ‘incentive to codify’ is focused on in this dissertation, this dissertation does not completely disregard other arguments put forward by scholars. The ‘incentive to codify’ argument is conceived of as complementary to other arguments, as far as such theories fit into the framework detailed in rest of the chapters. Economic analysis of law is used as a lens through
which the efficiency of protecting TK is examined. Such perspective does not necessarily reject justifications based on other theories.

In conclusion, it should be highlighted that although few, some scholars have used an economic lens in their search for rationales for TK protection. This dissertation builds upon such literature by situating TK in the public goods literature and by making the need to encourage the codification and disclosure of TK the core factor driving the need for legal intervention. Such analysis is expected to be one of the major contributions of the dissertation.
CHAPTER TWO: TRADITIONAL KNOWLEDGE AS A PUBLIC GOOD

1 Introduction

The previous chapter concluded by identifying the limited availability of economic justifications for TK protection. The chapter also highlighted the lack of a well-developed rationale based on the need to encourage TK codification as a consensus building issue. Chapter Two asks what the core causes for the alarming rate of TK loss are and whether there are economic rationales for providing legal protection. The chapter begins with a discussion of three core causes of the alarming rate of TK loss: the lack of codification, the destruction of knowledge holder communities, and a rising protectionist trend among knowledge holder communities and megadiverse countries. The combined effect of these factors is causing a dramatic loss of TK that necessitates an urgent solution. The discussion of the lack of codification (the predominantly oral culture) of TK holder communities; and the rise in restrictive measures in TK holder communities and megadiverse countries (labelled ‘a protectionist trend’ in this dissertation) are two key contributions that the dissertation attempts to make.

This chapter situates TK within the public goods literature in general and within the ‘knowledge as a public good’ scholarship in particular to examine the deficiency of investment in addressing the lack of TK codification, and to explain the rise in the protectionist trend. The chapter then examines the different alternative methods of producing knowledge goods with emphasis on the potential and limitations of these alternative channels for TK codification and dissemination. The chapter concludes by extracting key policy implications based on analysis of the core causes of TK loss and its public good nature. In doing so, the chapter prepares the groundwork for the discussions on the ‘incentive to codify’ argument in Chapter Three.

234 “Megadiversity” refers to the state of a locality in which it is host to a disproportionately high level of biological diversity. The uniqueness of a species to a certain country – endemism – is at the heart of the method used in determining which countries are megadiverse. Mega-diverse countries make up close to 70% of the biodiversity in the world. Biodiversity A-Z, Factsheet: Megadiverse Countries (United Nations Environmental Program and World Conservation Monitoring Center, 2014) See also text accompanying note 226.
2 Core Problems: The Tragedy of Traditional Knowledge

As outlined in the introductory section of Chapter One, TMK has proved to be valuable on its own and as an input for the pharmaceutical industry. It has helped the usually unreliable and costly bioprospecting projects to become more efficient in discovering new drugs and bringing them to market. Research shows that the efficiency of screening plants for medicinal properties rises drastically if TMK is used; the evidence also suggests that a substantial portion of the drugs currently being marketed have identical or similar uses in TMK.\(^{235}\) Despite having such value, TK in general and TMK in particular face an alarming rate of loss. As will be argued in this chapter, and Chapter Three, the need to sustain such knowledge and to facilitate its use by outsiders necessitates legal intervention.

When designing an intervention scheme, careful consideration should be given to the factors causing the alarming rate of TK loss. Although there are several factors that contribute to the loss of TK, this dissertation identifies the following three major causes: 1) the fact that TK is predominantly uncodified; 2) the destruction of knowledge holder communities (including their biodiversity resources); and 3) the protectionist trend that seems to be on the rise in TK holder communities and megadiverse countries. The high rate of loss seems to be a result of the combined effect of these causes rather than being attributable to any one of them. Below is an examination of how these causes contribute to the tragic rate of TK loss.

2.1 Lack of Codification and TK Loss

One of the core features of TK is that it is orally transmitted from one generation to the next through kinship and personal relationships.\(^{236}\) This is not to say that there is no codified TK. South


Asian traditional medicinal knowledge such as Ayurveda and Unani are good examples of documented TK. However, systematically codified TMK seem to be the exception rather than the rule. One unique feature of TK is that, for the most part, it is uncodified yet publicly available. Public availability, however, is different from public accessibility. The level of accessibility may vary depending on the type of TK and social norms in the particular knowledge holder community. For instance, TMK tends to have limited accessibility because it is usually exclusively practiced by traditional healers or village elders, and because transmission is usually made through kinship relationships and cultural initiations.

This is in stark contrast to ‘modern’ knowledge in which a culture of systematic documentation and dissemination prevails. This does not mean that ‘Western’ knowledge systems do not have uncodified know-how; a considerable portion of ‘Western’ knowledge is actually uncodified or ‘uncodifiable,’ (this topic is discussed in further detail in Section 2.2 of the following chapter). Systematic documentation, however, is the norm in modern knowledge systems. This culture of documentation is observable in various corners of ‘modern’ communities. For instance, in the academic setting, which is one of the core channels of knowledge production and dissemination, ‘publish or perish’ has been the custom since at least the early 20th century with the objective of encouraging researchers to externalize their knowledge for disclosure and wide dissemination. Intellectual property laws – which function as the main legal tools for regulating the production, use and dissemination of inventive knowledge goods – are filled with requirements for documentation. Examples of these requirements include the disclosure requirement under patent laws and the copyright law requirement that expressions be fixed in a tangible medium. The effect of patent law in encouraging inventors to codify their knowledge is an important point in this dissertation and is discussed in further detail in Section 2.2. of the next chapter.

\[\text{237 Inventory of existing online databases containing traditional knowledge documentation data (WIPO/GRTKF/IC/3/6), WIPO/GRTKF/IC/3/6 (Geneva: World Intellectual Property Organization - Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore, 2002) at 6.}\]

\[\text{238 International Institute for Environment and Development (IIED), supra note 34 at 6.}\]

\[\text{239 Some Western knowledge is not codified because of high cost of codification or because it is know-how learned through experience while other type of Western knowledge is uncodified because “some cognitive capacities resist explicit articulations” of the knowledge. See, Dan L Burk, “The Role of Patent Law in Knowledge Codification” (2008) 23:3 Berkeley Technol Law J 1009 at 1014–15.}\]

The fact that systematic documentation is not predominant among many knowledge holder communities contributes significantly to the tragedy that TK faces, especially when combined with the continued destruction of knowledge holder communities and their biodiversity resources. The lack of codification means that the challenges of transferring knowledge will continue to reduce the quality and quantity of TK transferred. It also means that, if the individuals who hold the knowledge die before transferring their TK, the TK that they hold will die with them. Furthermore, lack of codification makes attribution of TK challenging and may make TK seem non-innovative. TK undergoes incremental change over the course of its history when a new generation adapts it to fit their needs; however, since the knowledge is undocumented, these incremental changes are not documented either. Consequently, incremental innovations are not recognized by observers.

Researchers have found that the rate of TK loss is alarming. For instance, research by Victoria Reyes-Garcia and her colleagues has revealed that, between the years 2000 – 2009, the loss of TK related to the use of plants among Tsimane’ Amerindians (an Amazonian community) ranged “from 9% (for the female subsample) to 26% (for the subsample of people living close to towns).”\textsuperscript{241} The researchers identified that TK loss is higher in communities living closer to cities than in remote villages. The increasing urbanization of rural communities spurred by globalization can only be expected to increase the rate of TK loss. TMK especially seems to be facing a high rate of loss. Dr. Mark Plotkin, an ethnobotanist at Conservation International was quoted by the New York Times as stating "[w]e often talk about disappearing species, but the knowledge of how to use these species is disappearing much faster than the species themselves…the knowledge that's being lost most rapidly is information on healing plants."\textsuperscript{242} Although there are multiple factors driving TK loss, it seems that the lack of codification has played a key role, thus suggesting the need for TK codification.

\textsuperscript{242} Goleman, supra note 91.
One solution to the problem of a lack of documentation amongst TK holder communities is the creation of a culture of codification that would protect the knowledge from an alarming rate of loss. Codifying TK, however, may at times be against the interests of TK holder communities. Some TK holder communities may have a disincentive to invest in codifying their TK because this is likely to deviate from the informal rules and norms that govern access to that knowledge in the community. Most importantly, it may imply that those who have control over the knowledge will lose it once it is codified. Additionally, excluding outsiders from benefiting from the codification becomes more difficult once the knowledge has been documented. This may create concerns among the community either because they regard the knowledge as belonging solely to the community, or due to concerns with free-riding. More generally, the cost of codifying TK could exceed the benefits that can accrue to those who invest in codification, which in turn creates a disincentive to invest in codification. This lack of incentive to invest in codification and the need to provide legal protection to address it form a key contribution of this dissertation, an issue analyzed in further detail in Section 3.1.2 below.

2.2 Destruction of Knowledge Holder Communities

One of the major factors contributing to the loss of TK is the fact that the communities who are stewards of the knowledge are at risk of being destroyed. The risk these communities face is not only that of physical destruction but also destruction of the social, environmental and economic systems that support the production, use and transfer of TK. Most indigenous and local communities have been victims of colonization, land takings, political ostracism, and cultural assimilation since colonial times to this day, and these practices increased the rate of cultural and economic devastation of these communities. Since it is village elders who hold the most TK, the knowledge base shrinks when they pass away before transferring their TK. Other causes may include migration, lack of interest among the younger generation, challenges to customary access


to land, the prohibition of the practice of customary laws and cultural evolution or economic change. As a result of globalization and its effect on cultural harmonization, different cultures from various corners of the world will continue to mix as they come in contact with each other. In this process, communities that were colonized face a higher rate of socio-cultural loss when faced with global harmonization of cultures because of the past and present marginalization of their cultures. Stopping this process, however, will be very challenging and its desirability is disputed by some scholars.

Moreover, TMK, particularly, is highly dependent on plant varieties. Therefore, the environmental pressures that threaten to destroy biodiversity resources create a unique risk for TMK. Indigenous and local communities rely heavily on natural resources for survival. Thus, environmental pressures such as climate change and deforestation have devastating effect on such communities. In some circumstances the removal of indigenous and local communities as a whole becomes necessary in order to avoid environmental catastrophe. Therefore, if legal interventions are to provide a comprehensive solution, biodiversity loss must be considered a key part of the challenge, especially for TMK.

245 International Institute for Environment and Development (IIED), supra note 34 at 5.
248 See generally Tomlinson & Akerele, supra note 113; Michael Flitner, Review of national actions on access to genetic resources and IPRs in several developing countries. (Gland, Switzerland: WWF-World Wide Fund for Nature, 1995) at 2.
249 Jan Salick & Anja Byg, Indigenous people and climate change (Tyndal Center for Climate Change Research, 2007).
2.3 Protectionist Trend

Exacerbating the challenge caused by the two factors discussed above is a third factor labelled in this dissertation as a ‘protectionist trend,’ which is a rising trend among knowledge holder communities and megadiverse countries. As stated earlier, current laws, policies, and practices do not provide effective protection to most TK. IP laws and policies which are used by ‘modern’ societies to regulate the production and use of knowledge originated in the cultural context of Europe. As discussed in detail in Chapter 1, Section 1.5, most TK is not patentable because it does not meet the requirements of ‘novelty’ and ‘inventive step,’ and there is a general conflict in orientation between IP laws and the needs of knowledge holder communities. Current practice favors users who are able to use TK without any obligation to share benefits with knowledge providers. Past experiences involving ‘misuse’ and ‘misappropriation’ of TK have made TK holders suspicious of outsiders and have encouraged them to keep their knowledge secret.

The response of megadiverse countries and source communities to the lack of recognition and legal protection for TK has been to adopt a protectionist position in which they increasingly take measures to restrict access to TK and genetic resources. A few scholars have noted, although in passing, that there has been an increase in domestic legislation restricting access to TK and genetic resources in megadiverse countries. Biodiversity-rich countries of the South and many knowledge holder communities see the lack of legal protection as an unfair state of affairs, some claiming that, in addition to failing to protect TK, intellectual property laws and practices,

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251 See generally, Sherman, supra note 62.
252 Carvalho, supra note 3 at 245–47 (stating that indigenous and local communities are becoming secretive and listing national attempts to restrict access to TK); Cottier & Panizzon, supra note 233 at 575–76, Section f (outlining national legislations enacted to protect TK in India, Brazil, Peru, The Philippines, and the Africa model legislation.).
253 For example, the Like-Minded Megadiverse Countries (LMMC) is a group of 17 developing countries that hold approximately 70% of the world’s biodiversity and was formed in the international negotiations for the formulation of Access and Benefit Sharing (ABS) requirements under the CBD and Nagoya Protocol. The group published a statement called “The Cancun Declaration” which reaffirms the view of the group and its expectations. According to the declaration the group acknowledges the inequities in the status quo and affirmed its goal of establishing an effective international Access and Benefit Sharing mechanism. See The Cancun Declaration of Like-minded Megadiverse Countries (Like-Minded Megadiverse Countries (LMMC), 2002).
support and further its misappropriation and misuse. The protectionist trend adds to the alarming rate of TK loss resulting from the predominantly uncodified nature of TK and the destruction of knowledge holder communities.

This protectionist trend should be worrying because increased access to TK and genetic resources, not increased restriction, is beneficial to collaboration and innovation in the field. Increased access is what close to two hundred countries of the world agreed to when they signed the Convention on Biodiversity (CBD). However, recent trends seem to show a disturbing trend towards increasing restrictions. As Charles McManis observes, the CBD:

Stimulated a wave of national legislation having the effect (whether intended or unintended) of restricting, rather than facilitating, access to genetic resources in the developing world, pending the industrialized world’s adoption of a meaningful benefit-sharing measure.

Restrictions on genetic resources would mean restricted access to TK because of TK’s close linkage to genetic resources; and most national legislation also mention restrictions on access to TK concurrently. The status quo may not be sustainable if this trend continues and more megadiverse countries legislate to restrict access. Even in the case of TK that has been disseminated outside the original community, because of the lack of codification, the


256 The Convention on Biological Diversity, supra note 113, Preamble, Para 12.

257 The Cancun Declaration, supra note 252; Carvalho, supra note 3 at 245.
dissemination might not easily cross national borders. In such circumstances, increased restriction on the national level would mean increased restriction on the public availability of TK as well.

In addition to restrictions at the national level, there are some attempts by indigenous and local communities to keep TK secret. For example, the various religious or cultural ceremonies by shamans that hold traditional medicinal knowledge are effective in concealing the knowledge from members of their own indigenous and local communities. These attempts may have limited effect in keeping a given medicinal plant and medicinal knowledge secret from a trained scientist who might have the knowledge and skill to identify and investigate therapeutic plants.\textsuperscript{258} Although some of these attempts to keep TMK secret currently fail, other measures may be created that will become effective in restricting access.\textsuperscript{259} If governments and communities in megadiverse countries are determined to limit access to TK they could do so by putting restrictions on traveling to such sites. Some communities successfully keep their knowledge secret through geographic and social barriers.\textsuperscript{260}

The fact that megadiverse countries take a protectionist stance on genetic resources and TK may not necessarily be worrying in itself. If such measures were effective in allowing either the source countries or communities to use the knowledge in producing products and services for the general public, such an approach would have functioned similarly to trade secrets in ‘modern’ industries. However, source countries and communities do not have the capacity to use TK in such a way and such uses of TK have not been reported to date. Additionally, there is a real risk that TK held in secret might be lost before it is transmitted or used because of the lack of TK codification and the pressures that threaten to destroy TK holder communities.\textsuperscript{261} In scenarios in which TK is lost

\textsuperscript{258} Ebermann, supra note 110 at 129.
\textsuperscript{259} Ibid.
\textsuperscript{260} Carvalho, supra note 3 at 245.
\textsuperscript{261} Many reports on indigenous people and local communities cite the loss of knowledge resulting from the death of elders and the inability to transfer the knowledge to younger generation of a community as a major cause for TK loss. For example, a study by the International Institute for Environment and Development (IIED) has found that as a result of the migration and dis-interest of younger generations of many communities the knowledge of elders is disappearing. See, for instance, a case study of the TMK of Panamanian communities Kuna and Embera-Wounaan. International Institute for Environment and Development (IIED), supra note 34 at 17; Researchers note that the death of an elder and traditional healer was a major cause for loss of TMK that was not transfer to his apprentice in
before being transferred or used, both the TK holders and the public lose. In the absence of use, codification and disclosure, this knowledge base will be lost with the communities and cultures that preserved it for ages.

Even in situations in which TK holder communities could successfully commercialize TK through a protectionist regime, such scenarios may not be the most efficient. Under a protectionist framework, only firms that are willing to go through the bureaucratic hurdles involved in getting access to TK and biodiversity resources will be able to do so. This may exclude other feasible projects because of increased transaction costs. Alternatively, the source community or country itself could commercialize its TK. However, because most knowledge holder communities and megadiverse countries have less financial and human capital to conduct R&D and market TK-based products, such alternatives might be sub-optimal. Therefore, even if source communities and countries could potentially benefit from a protectionist trend, the global public may miss a considerable benefit because of the inefficiencies involved in such a process.

To sum up the discussion in the above sections, the dramatic rate of TK loss is a result of the combined effect of the above stated major pressures: the lack of codification, the continued destruction of knowledge holder communities and the rise of a protectionist trend. In the face of such threats, promising attempts exist in preserving and re-establishing cultural communities. The codification of TK which, in turn, will create social and economic interest in the knowledge provider communities may supplement long-term initiatives for cultural promotion. For instance, in the Hoodia story discussed at the beginning of Chapter One, the funds received from the licensing of the P57 extract were allocated for investments in education and job creation for the San people, issues that the San Council felt were a long-term priority. Other benefit sharing schemes from TK could be used in issues that the source community feels are important.

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The next section situates TK in the public goods literature to examine the deficiency of investment in addressing the lack of TK codification and to explain the rise in the protectionist trend. Discussions from a public goods perspective are expected to provide useful information that could point to potential solutions. In addition to the general public good literature, the section that follows will situate TK in the ‘knowledge as a public good’ scholarship.

3 Public Goods and Traditional Knowledge

A public good in the economic context refers to a non-rivalrous and non-excludable good. Some examples of public goods include national defense, the protection of the environment and basic infrastructures. Non-rivalry refers to the capacity of the good to be used by a person without reducing the ability of another to use it i.e. despite being used by one person, it is not consumed. If we take national defense as an example, once a given country establishes a military force through public funding, the peace and security that results from the existence of such a force is enjoyed both by taxpayers and those who do not pay tax. The enjoyment of this peace and security by one citizen does not diminish the enjoyment of the same by another. Non-excludability refers to the nature of public goods in that it is hard, costly or at times impossible to exclude others from using such goods. Using the national defense example, if a government sought to exclude those who have not paid taxes from enjoying the peace and security in a country, it would prove impossible to do so. Economists call this feature the inappropriability problem.

The concept of public goods is a complex matter. Albeit at different levels, many goods entail consumption externalities (i.e consumption resulting in a benefit or cost to a third party, in which case the good may be labelled a ‘public good’). For instance, while CO$_2$ emission from factories results in the external cost of polluting the environment for the general public, the provision of

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262 This is different from and may be contrasted to the use of the term “the commons” or “common good” in other contexts which may refer to goods that are owned by the public as a whole or that may be utilized by everyone. Although the concept of public goods existed in previous decades, its theoretical development is credited to Paul Samuelson who outlined the concept in 1954. See Paul Samuelson, “The Pure Theory of Public Expenditure” (1954) 36:4 The Rev of Econ and Stat 387.

263 Ibid; Drahos, supra note 233 at 52.
quality education has the positive external benefit of a literate community. This heterogeneous nature of public goods calls for diversity in their regulation rather, than implementing a one-size-fits-all approach.  

Scholars have attempted to group public goods using several factors. One method of clustering public goods is using the range of impact the good has (local, regional, global). The environment is often a global public good; it involves significant consumption externalities at the global level. A good that is particular to a certain community or country is a local public good. This category includes public goods that rely heavily on local norms, institutions and resources. Another way of grouping public goods is based on their relationship with social norms (i.e. goods dependent on norms and those independent of norms). Governments are usually considered to be norm-dependent public goods because the effectiveness of a government depends on the quality of the social fabric in the locality, while the applicability of a mathematical formula is independent of social norms.

Another method of grouping public goods is based on the level of excludability of the public good, in which case a good can be a pure or impure public good. A pure public good is one which is always non-rivalrous and non-excludable, while an impure public good is one which might lose one of these two core elements, depending upon certain circumstances. For instance, the environment is a pure public good because it is almost impossible to exclude others from enjoying its benefits. On the other hand, some public goods may be subject to rivalrous consumption or

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264 Todd Sandler, “Global and regional public goods: A prognosis for collective action” (1998) 19:3 Fisc Stud 221 at 223 (outlining a range of factors that should be considered to group public goods into global and regional in order to decide to intervene or not).
265 Charles M Tiebout, “A Pure Theory of Local Expenditures” (1956) 64:5 Journal of Political Economy 416 at 416; Drahos, supra note 233 at 52; Sandler, supra note 264 at 223 (outlining a range of factors that should be considered to group public goods into global and regional in order to decide to intervene or not).
266 Drahos, supra note 233 at 52.
267 Ibid.
269 Ibid at 308–9.
may be excludable. For example, public infrastructures such as roads are impure public goods because, although several individuals could drive on a road without restricting the ability of another person to do the same, if there are too many cars on the road a traffic jam could occur making the use of the road rivalrous. Establishing a toll on roads (and other public infrastructures) could also make them excludable.

Lastly, there are public goods that depend on the capability of potential users and those that can be used regardless of such capability.\textsuperscript{270} The public good provided by healthy environments does not require any other capability for consumption. Some types of knowledge, however, may require a certain capability in order for the potential beneficiaries to use them effectively.\textsuperscript{271} It should be noted here that a certain public good might have intersectional qualities that span the different groupings discussed above.

The purpose of the above discussion of public good classifications is to make the case that, although public goods share common features, there are differences among them that call for varied responses that fit the nature of the public good being addressed. Even if TK shares much with other information goods, its regulation need not necessarily reflect the regulation of other information goods. TK could generally be described as an impure global public good that may at times depend on the capability of the users. A more detailed discussion of the public good qualities of TK is provided below under section 3.1.2.

The core goal of placing goods into private and public groups is to formulate a fitting response for their production, use and dissemination. The general assumption is, because it is hard or impossible to exclude payers from non-payers, the production of public goods through private means is limited. Private actors who are presumably usually interested in maximizing their private profits or gains will look at private returns and not returns for the public.\textsuperscript{272} The non-rivalrous nature of public goods also means that economic efficiency dictates charging a price of zero -

\textsuperscript{270} Drahos, \textit{supra} note 233 at 53.
\textsuperscript{271} \textit{Ibid}.
\textsuperscript{272} Stiglitz, \textit{supra} note 268 at 311.
marginal cost of distribution – which will not encourage private actors interested in profit maximization to create and disseminate them.\textsuperscript{273} As a result, the “central public policy implication of public goods is that the state must play some role in the provision of such goods.”\textsuperscript{274} The two major alternative ways that governments could intervene are through the recognition and enforcement of private (exclusive) rights or directly through government provision.\textsuperscript{275} In addition to the role that the government could play, alternative channels of private production of public goods do exist.\textsuperscript{276}

### 3.1 Knowledge as a Public Good

He who receives an idea from me receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.

\textit{Thomas Jefferson}\textsuperscript{277}

Knowledge is commonly considered to be a public good and is at times labelled “the quintessential public good.”\textsuperscript{278} The quote from Thomas Jefferson above speaks to the non-rivalrous consumption of knowledge. The public good nature of knowledge has been noted by economists for decades.\textsuperscript{279} Sharing one’s knowledge with another does not lessen the amount of knowledge

\begin{itemize}
  \item \textsuperscript{273} \textit{Ibid.}
  \item \textsuperscript{274} \textit{Ibid.}
  \item \textsuperscript{275} \textit{Ibid} at 311–12.
  \item \textsuperscript{276} Raymond G Batina, \textit{Public goods : theories and evidence} (New York: Springer, 2005) at 99 (With dedicated section on the private provision of public goods.) For a detailed discussion of private production of knowledge see Section 3.1.1 below.
  \item \textsuperscript{277} Thomas Jefferson, the third president of the United States, who was also an inventor, made the quoted statement in which he expresses his belief that ideas are public goods and that utilization of ideas does not diminish their content. Thomas Jefferson, Letter to Issac McPherson, 13 Aug. 1813. See HA Washington, ed, \textit{The Writings of Thomas Jefferson} (The United States Congress, 1853) at 180.
  \item \textsuperscript{278} Drahos, \textit{supra} note 233 at 47.
  \item \textsuperscript{279} Vogel, \textit{supra} note 233; Batina, \textit{supra} note 276 at 2; Stiglitz, \textit{supra} note 268.
\end{itemize}
consumed by each person; and once knowledge is disclosed to the public it is usually difficult, costly or impossible to exclude those who do not pay to access it.

Based on the categories described above, knowledge can be grouped as an impure, global, and at times capability-dependent public good. Knowledge is an impure public good because some part of it could be excludable depending upon the circumstances. In addition to physical barriers such as locks that could be used to restrict access to knowledge goods, the use of trade secrets is one avenue through which outsiders could be excluded from accessing knowledge. For instance, a factory can keep its information related to inputs and composition secret by having its employees sign non-disclosure and non-competition agreements. Even if competitors may be able to reverse-engineer its products, producing a competing product may be difficult without the know-how that expert employees hold. This excludability element of knowledge could extend to tacit knowledge which is mostly accumulated through experience. More discussion on how knowledge could be made excludable is provided below in section 3.1.1.

The fact that most knowledge can be applied globally regardless of location makes it a global public good. Unless use of the knowledge requires some environmental resources only available at a certain location, knowledge can be used in different parts of the world. Knowledge of the effects of gravity, for example, can be used throughout the world.

Use of knowledge can at times depend on the skill or capability of the user. The level of knowledge codification is important when making such distinctions. Codification, an important term used frequently through this dissertation, refers to the systematic and purposeful documentation of know-how and associated information. While some knowledge goods are codified in a systematic and detailed manner others are uncoded practices held by a single

280 For more discussion on tacit knowledge and its interaction with codified knowledge, see Chapter Three, Section 2.2

individual or within webs of social interactions. Peter Drahos developed a helpful distinction between codification and embodiment by grouping knowledge which is embodied in products and services as ‘artifact-embodied’ knowledge and knowledge which is embodied in skills of a person as ‘skill-embodied’ knowledge. Thus, the second type of knowledge (i.e. ‘skill-embodied’ knowledge) can be said to be a capability-dependent public good. That is to say that a certain level of skill or capability is required in order for users to fully enjoy the good. Highly advanced technical knowledge is a good example of a capability-dependent public good. Tacit knowledge, which requires the user to have a certain level of experience with the good, also depends on the capability of the user.

One of the major rationales for the granting of intellectual property rights is the fact that knowledge is a public good and therefore government intervention on behalf of the public is necessary to encourage the production and dissemination of knowledge. In his letter to Isaac McPherson, Jefferson writes that such rights are “not of natural rights, but for the benefit of society.” A core rationale for the granting of a patent is to encourage inventors to invest their time and energy in creating new and useful inventions with the hope of recouping such investment through the means of exclusive rights. Article 1 section 8 clause 8 of the US Constitution, which addresses patents and copyrights, gives Congress power to legislate in the area with the goal of promoting “the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

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282 Drahos, supra note 233 at 53.
283 Washington, supra note 277 at 181.
285 For example, see Constitution of the United States of America, supra note 213 Article 1, Section 8, Clause 8.
encourage broader economic activity”286 by granting a limited patent right. The objectives in Canada and the US seem to be similar.287

Lastly, the efficiency trade-off that exists in patent law may be worth mentioning. When patents, which are artificial monopolies, are granted, they restrict public access to the invention. This restriction creates a static inefficiency - inefficiency occurring at a particular period of time. Patent law artificially restricts the general public from using the invention despite the fact that the efficient scenario is for any capable person to use the invention (which does not affect the ability of the inventor to use the invention). The fact that a smaller number of people (i.e. those who can afford to pay to use the invention) are using the invention than would be efficient (i.e. any capable person) is what is referred to as static inefficiency. Despite the creation of static inefficiency, the expected dynamic efficiency that would result from the increased investment in inventions and public disclosure is expected to be make-up for the loss in static efficiency.288 Dynamic efficiency here entails the increase in the production of new and innovative knowledge that would otherwise not materialize without the artificial monopoly promised by a patent right. Patents can also impede dynamic efficiency by restricting access to information goods or by increasing the cost of their use by subsequent innovators. Generally, the balance that patent laws seek to strike through various means involves evaluating these two efficiency outcomes. A similar balancing act will be required in the case of TK.

3.1.1 Alternative Methods of Knowledge Production

Private (exclusive) rights are not the only reason that knowledge is produced in current times. There are several alternative channels that are responsible for the production of knowledge in its different forms. These channels include those that make knowledge production possible despite its non-excludable nature and those that make knowledge excludable to some extent. Below is a

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288 Stiglitz, supra note 268 at 311.
discussion of the various channels of production other than private exclusive rights, beginning with channels through which public goods are created or sustained despite their non-excludable nature.

One common alternative to private investment for the creation of knowledge is public funding. This is especially justified when society “weighs the welfare of future generations more heavily than private investors do.” Public investments in basic research conducted in universities and research institutes are based on such a rationale. In addition to playing the important role of educating generations of students, universities have been sites of innovation. Government investments in basic information infrastructures such as the internet and networks seem to have been immensely valuable for the creation and dissemination of knowledge.

Another instance that knowledge may be created is if the producer is able to recoup enough returns from its investment in the knowledge production despite some free-riding from others. In such cases, even if others would benefit from the knowledge without sharing in the cost of production, this does not affect the producer who is able to profit from its investment.

It is essential to recognize that not all private actors are interested in private returns. In fact, there are numerous reasons that make private actors produce socially and economically valuable goods, including knowledge, without the incentive of private returns. These reasons may range from altruistic motives to private non-economic gains. For instance, the creative commons and open innovation initiatives that seem to be gaining in popularity in recent years are dominated by altruistic motivations or at least are not responses based merely on private economic benefits. Private actors may be encouraged to produce different public goods because of self-motivation, personal satisfaction, or the desire to solve problems. Examples include the professor who publishes writings in open access journals or the game enthusiast who makes improvements to an

290 Batina, supra note 275 at 99 (Discussing charity as a good example of altruistic private production of public goods.).
original game.291 These are examples of the production of public goods for reasons other than private gains in the financial sense of the term. Another channel of public good production may be through institutions run by private donations such as charities or civil societies that work to create and disseminate knowledge in various fields without the incentive of exclusive private returns.292 In such instances, individuals involved may be looking for personal satisfaction, peer recognition or community improvement as incentives for doing what they do.

Norms developed within close-knit groups are yet another alternative for the production and dissemination of knowledge despite its non-excludability. Recent research has revealed that these norm-based (as opposed to law-based) intellectual property systems, for example, are practiced in circles of high-end chefs293 and stand-up comedians.294 Emmanuelle Fauchart and Eric von Hippel show that social sanctions have been effectively used to enforce the “rights” of French chefs over their recipes in a similar way to intellectual property laws.295 Dotan Oliar and Christopher Sprigman have observed a comparable norm in the community of stand-up comedians in which “bad-mouthing” and “refusal to work together,” among other methods, are used to enforce ‘rights’ in original jokes.296 Although norm-based intellectual property systems may be at times as effective (if not more effective) than law-based systems, it seems that these norm-based systems require the existence of a close-knit community to sustain the effectiveness of social sanctions. As a result, norm-based intellectual property systems might be less effective in the case of global public goods, such as TK, that cross social, regional or national borders.

The many alternatives discussed above (government provision, profit despite free-riding, self-motivation, personal satisfaction, desire to solve problems, and norm-based systems) are

291 For more discussion on how game aficionados are used by companies to create communities, see Drahos, supra note 233 at 58.
292 Batina, supra note 276 (Discussing charity as a good example of altruistic private production of public goods.).
295 Fauchart & Hippel, supra note 293.
296 Oliar & Sprigman, supra note 294.
circumstances in which knowledge is produced despite the fact that it remains non-excludable. As stated at the beginning of this section, there are situations in which knowledge may become excludable, therefore giving private actors an incentive to produce it. Below is a brief discussion of scenarios in which knowledge may become excludable to some extent and is, as a result, produced by private actors in the absence of intellectual property rights.

Depending on the type of industry, knowledge may involve a high cost of copying. The cost of copying may be high in extremely technical industries and, as such, competitors might find it inefficient to copy. This makes regulatory intervention unnecessary. Even if copying is not originally costly, measures may be taken to increase the cost of copying.\(^{297}\) If it is cheap to prevent valuable knowledge from falling into a competitor’s hands then firms might have enough incentive to keep it secret. Trade secrets are common alternatives to patenting.\(^{298}\) A good example of this is the Coca-Cola formula which has enormous commercial value and has been kept as a trade secret for well over a century.\(^{299}\) Some inventors choose to keep knowledge as a trade secret because of the absence of a disclosure requirement and because there are no term limits.

The first-mover advantage (lead-time) is another reason that firms might decide to produce products and services embodying knowledge. Under such a scenario, even if competitors might be able to imitate the original product, the lead time may be enough for the producer to recoup adequate returns.\(^{300}\) For instance, the brief window of lead time available for creators of fashion design has proved to be enough incentive to sustain the industry.\(^{301}\) Lead time may also result from the sophistication of the product that is offered. Drahos uses the example of CEA Technologies - a small Australian technology company that produces and supplies sophisticated

\(^{297}\) Posner, \textit{supra} note 289 at 66.
\(^{298}\) Hagen et al, \textit{supra} note 287 at 573.
\(^{300}\) Posner, \textit{supra} note 289 at 66.
radar technology and keeps its knowledge highly secret.\textsuperscript{302} Because of the complexities in producing its products, by the time the competition succeeds in reverse-engineering CEA’s products, CEA makes new technological advancements that out-perform older versions.\textsuperscript{303}

Because of the unique features that different types of public goods hold, a one-size-fits-all approach may not work. Each public good has its own unique elements that may call for a unique system of regulation (or absence of regulation) in a way that best fits its nature. While TK shares many elements with other knowledge goods, there are circumstances in which it displays unique features that call for a more nuanced approach. The uncodified state of most TK, the predominantly incremental change that defines it, and the non-technical nature of the knowledge are important features worth noting. The fact that there is a dramatic rate of TK loss\textsuperscript{304} implies that the above discussed channels of incentives and circumstance which have succeeded in sustaining the production and dissemination of ‘Western’ knowledge have not worked for TK or at least have not been attempted at all. The section below discusses TK as a public good and the possible unique features that require special attention.

3.1.2 Traditional Knowledge as a Public Good

As defined in the introductory section, TK refers to the know-how, skills and practices of indigenous and local communities. Similar to other information goods, the body of knowledge could be enjoyed simultaneously by different parties and, once disclosed to outsiders, it would be impossible to exclude them (i.e. it is a public good with non-rivalrous and non-excludable features). The core thesis of this dissertation builds on this public goods nature of TK and the resulting disincentive. As discussed at the beginning of this chapter, the lack of TK codification is one of the key factors driving the alarming rate of TK loss. Therefore, an obvious solution to such a problem is the comprehensive codification of this body of knowledge in order to save it from loss and to make it available for posterity. Codifying TK will, however, increase its non-

\textsuperscript{302} Drahos, supra note 233 at 54.
\textsuperscript{303} Ibid.
\textsuperscript{304} Dutfield, supra note 59 at 520.
excludable nature because once TK holders codify their knowledge their knowledge is externalized and they lose control over what happens to it. In other words, codification of TK increases the inappropriability (non-excludability) problem. Consequently, TK holder communities have a disincentive to invest in the codification of TK. This disincentive extends to governments of megadiverse countries that are key sources of TK. These countries have a disincentive to invest in the codification of TK because they will not be able to prevent free-riders from using the codified knowledge without sharing the cost of codification. This disincentive is especially important because most megadiverse countries are developing countries in the Global South that have more pressing issues requiring government investment than TK codification.

Additionally, documenting TK despite free-riding by outsiders does not seem to be a promising endeavor considering the higher risk of failure to commercialize TK. Because of the unpredictability related to which TK would succeed in the market, TK codification may need to be large in scope. The cost of codifying TK may, therefore, outweigh the resulting benefit which creates the absence of incentives to invest in codification in the first place.

A legal intervention is, therefore, needed to address this disincentive or lack of incentive that TK holder communities and megadiverse countries may face. A carefully crafted legal intervention that gives TK holders control over codified TK will be able to address this problem and encourage TK holders and governments of megadiverse countries to codify their knowledge. Once the knowledge is saved from loss, TK holders may wish to disclose it to others in order to engage in commercialization of the knowledge or they may prefer to engage in commercializing it themselves. Some TK holders may instead be interested in keeping their knowledge secret for many reasons including because they consider it to be a sacred TK that should not be commercialized. Codification is beneficial in all these scenarios because the valuable body of knowledge is saved from loss.

The most efficient framework from the alternative scenarios seems to be one in which a clear legal framework works in the background to facilitate a collaborative and sustained relationship between knowledge providers and users. The rise of the worrying protectionist trend discussed at the beginning of this chapter could be countered through the establishment of a reflective legal
framework that could address the interests of all stakeholders. In addition to solving the inappropriability problem of TK, legal intervention can also provide an alternative to inefficient attempts at keeping TK secret. Patents are at times seen as incentives for encouraging companies to document and disclose their secret knowledge.\(^{305}\) To a limited degree “the same anti-secrecy rationale that applies to patents can also be valid in the field of TK.”\(^{306}\) Here, the differences between TK and the knowledge that companies in modern industries keep secret calls for different treatment. One difference is in terms of capacity. While modern industries usually have sophisticated physical, technological, and procedural barriers to keep their information secret, indigenous and local communities may not have the financial and technical capacity to establish similar barriers. Another major difference is that TK might be less difficult to understand than the complex knowledge that, for instance, a biopharmaceutical firm holds. The complexity of the knowledge in the latter case makes it inaccessible, thereby lessening the need for patent protection. A patent-like system as anti-secrecy tool may in this sense have a greater effect on TK than complex information that only a few individuals may understand. It should also be noted, however, that the systematic documentation of advanced Western knowledge may, at times, make it easily understandable by experts.

An examination of TK through the classification of public goods discussed earlier in this section may help in better understanding its public good nature and in crafting a suitable legal framework.\(^{307}\) Since TK, as defined in this dissertation, is know-how, it is generally a global public good that could be used across local and national borders.\(^{308}\) Some commentators argue that TK is intertwined in the cultural context in which it is developed and held, and the system of protection should, therefore, include “normative and social components”\(^{309}\) in addition to the knowledge component. However, this seems inconsistent in the context discussed above. If a public good is local and only applies to a certain knowledge holder community, then intervention


\(^{306}\) Carvalho, supra note 3 at 247.

\(^{307}\) See Section 3.1 on Public Goods and Traditional Knowledge.

\(^{308}\) Stiglitz, supra note 267 at 310 (Commenting on the global public good nature of knowledge).

\(^{309}\) Taubman, supra note 4 at 523–25.
may not be necessary in the first place. The local social norms that helped preserve it would continue to do so. Cases of biopiracy exist because TK is applicable beyond the originating knowledge community. Thus, TK, at its core, is a global public good that could be used in any part of the world, given the availability of resources associated with it.

TK is also an impure public good because it is possible to exclude outsiders by keeping TK secret or by restricting access to places in which it is practiced. It is common to see knowledge holder communities taking measures in order to keep outsiders or certain members of their community from accessing restricted knowledge. Measures to restrict access are especially observable with TMK in which traditional healers only reveal knowledge to an apprentice and adopt various ceremonies to keep unauthorized individuals from understanding the knowledge. Traditional healers are usually the ones who enjoy the privilege of receiving and practicing TMK, and transfer of the knowledge to other members of the community is done through kinship relationships and initiations.

If looked at through Drahos’ grouping of public goods most TK would fall under the uncodified and skill-embodied knowledge group. The use of TK may require knowledge and skills, although not as advanced as most modern scientific knowledge, and as a result becomes a capability-dependent public good. Therefore, regulations that seek to encourage its production and dissemination need to be reflective of these features.

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311 For instance, a researcher from the Smithsonian Institute discussed how he was not able to understand the type of plant a local shaman used to treat a symptom because “[b]y local custom, [the shaman] could only reveal that to an apprentice.” See, Goleman, *supra* note 91.


313 Githae, *supra* note 236 at 78; Carlos Maria Correa, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* (World Health Organization, 2002) at 4.
As examined at the beginning of Chapter One, the difference between TK and know-how in modern industries is in the way knowledge is produced and used. While modern industries focus on ‘scientific’ evidence-based production, TK is dominated by trial-and-error and intuition.\textsuperscript{314} Both types of knowledge are public goods in the sense discussed above. However, current legislation, policies and practices protect ‘modern’ inventions and related know-how\textsuperscript{315} while traditional knowledge and innovation does not enjoy protection. TK and innovation are mistakenly considered to be static\textsuperscript{316} and already publicly available. In reality TK is the “oldest form of ‘cumulative and sequential innovation’ known to man”,\textsuperscript{317} however, it is not widely accessible to the public. As a result of the mistaken belief that TK is static, it is argued that no additional incentive is needed for its production.\textsuperscript{318}

However, this line of argument misses an important aspect which is that the absence of legal restrictions on access does not actually guarantee public access. If knowledge is not protected but is still not accessible to the general public, then its dissemination becomes as essential as its production.\textsuperscript{319} Intellectual property rights are justified, not only on the grounds of encouraging the generation of new knowledge, but also on the detailed disclosure of such knowledge to the public, which can access the disclosed invention to build on it. In fact, recent scholarship claims that intellectual property laws function more effectively in encouraging disclosure than inventions.\textsuperscript{320} As such, even if one thought of TK as a static body of knowledge that has already been created, there is a strong case to be made for the encouragement of its codification and

\textsuperscript{314} Carvalho, supra note 3 at 244 (listing the four elements of TK including the fact that it based on “trial-and-error” approach).
\textsuperscript{315} Burk argues that patent laws protect inventions but they also protect know-how related to inventions. For a more detailed discussion of this claim and how it relates to TK, see section 2.1 below. Burk, supra note 239.
\textsuperscript{316} Correa, supra note 313 at 3 (Stating that TK is a dynamic body of knowledge because knowledge holders adopt it to their changing environment); Carvalho, supra note 3 at 260 (Stating the dynamic nature of TK as one core feature).
\textsuperscript{317} Reichman & Lewis, supra note 5 at 356.
\textsuperscript{318} Review of Existing Intellectual Property for Traditional Knowledge, WIPO/GRTKF/IC/317 (World Intellectual Property Organization, 2002) at 11 at Para 32; The Crucible II Group, supra note 217 at 73.
\textsuperscript{319} Stiglitz, supra note 268 at 317; Ebermann, supra note 110 at 128.
\textsuperscript{320} Jessica Silbey, The eureka myth : creators, innovators, and everyday intellectual property (Stanford, Calif.: Stanford Law Books, 2015) (Claiming that intellectual property plays a limited part, if at all, in the initial stages of creativity, but may play a part in decisions of distribution); Burk, supra note 239.
disclosure. The fact is TK involves a certain level of innovation because knowledge holders adapt TK to the changing circumstances of their communities.\textsuperscript{321} As a result, it is in a constant state of incremental innovation, which makes the argument for the protection of TK stronger. The thesis put forth in this dissertation, however, is based on the need to encourage codification of knowledge to save it from loss and to encourage its disclosure to outsiders who may be interested in using it. The thesis is not based on the encouragement of the generation of new TK.

When TK holders produce and sustain the body of knowledge, they do so for personally or communally self-interested reasons, such as providing traditional health care or practicing their culture. The potential benefit that TK might have for bioprospecting projects and for beneficiaries of the end product seems to be a positive externality.\textsuperscript{322} Users of TK, such as pharmaceutical companies, research institutes and consumers who use TK-based end products, are therefore, free-riders.\textsuperscript{323} This scenario could be acceptable from a purely utilitarian perspective. Knowledge holders who have been creating and sustaining TK could continue to do so without the need for legal intervention, and users could continue to benefit from TK.

However, as discussed in detail in Section 2 above, TK is being destroyed as a result of three core problems. The fact that TMK is found in predominantly uncodified form, that many knowledge holder communities are disappearing at a high rate, and that knowledge holder communities are increasingly hesitant to share their knowledge, threaten the continued accessibility of TK. The status quo in which TK holders continue to sustain and share TK with outsiders, while users continue to benefit from such knowledge is at risk in its current form. By allowing knowledge holder communities to internalize at least some of the external benefit that users enjoy, it is possible to create an incentive for knowledge holder communities to codify and share their TMK.

\textsuperscript{321} Taubman, supra note 4 at 523; Declaration on Science and the Use of Scientific Knowledge [Declaration on Science and the Use of Scientific Knowledge].

\textsuperscript{322} Ebermann, supra note 110 at 153.

\textsuperscript{323} Commentators have highlighted the considerable benefit that TMK users gain from their continued access to the knowledge and resources of indigenous people and local communities. See for instance, \textit{ibid}; See also, Remigius N Nwabueze, “Ethnopharmacology, Patents and the Politics of Plants’ Genetic Resources” (2003) 11 Cardozo J Int Comp Law 585.
The public good nature of TK, therefore, directs attention towards a disincentive for knowledge holder communities to invest in codifying and sharing their knowledge with outsiders.

There is evidence that the patent law system has encouraged inventors to codify what they would otherwise not codify. The disclosure requirement under patent law which requires inventors to disclose their claimed invention in detail has resulted in the codification and disclosure of such knowledge to the general public. Knowledge of the invention is documented for others to examine and use in the future. Since a similar legal intervention is missing in the case of TK, knowledge is usually lost forever with the death of elders and traditional holders. In a sense, TK is being under-used when this valuable knowledge is lost together with knowledge holding communities, or when such communities restrict access to TK, preventing a useful TK-based product from being produced. A carefully designed legal intervention could, however, address these problems and save such knowledge from loss by encouraging the codification of TK. Such reasoning is discussed in further detail in the next chapter and is one of the central contributions of this dissertation.

3.1.3 Alternative Production of Traditional Knowledge

The dramatic rate of loss of TK implies that the methods of knowledge production discussed above have not resulted in the effective production, use, and dissemination of TK as they have been able to do in other areas of knowledge production. These alternatives either did not work for TK, or they did not work to a sufficient degree so as to generate incentives for knowledge holder communities. It may also be that a concerted effort to produce TK through such alternative channels has not yet been attempted. A more detailed discussion of how some of these channels could be organized in order to support the production of TK will be provided in the following chapter. The discussion below is limited to the possible explanations for the failure of alternative channels of production of knowledge in the case of TK.

324 Burk, supra note 239 (Analyzing the effect of patent laws in encouraging inventors to codify their knowledge).
Secrecy

As mentioned earlier, secrecy is a common channel for the production and use of valuable knowledge by private firms. Scholars have recently pointed to the potential of trade secret law as a protection mechanism for TK.\(^{325}\) The core assumption in such a scenario is the ability of the knowledge producer to keep knowledge from being accessed by competitors or the general public. In the case of TMK, attempts at keeping the knowledge secret seem to be the trend rather than the exception in knowledge holder communities. The adoptions of spiritual and cultural ceremonies during the use of TMK and the strict personal relationships that seem to dominate the transfer of TMK from healers to apprentices imply that knowledge holder communities have attempted to keep TK secret.\(^{326}\) Such attempts, at least among some indigenous communities, are mechanisms of TMK appropriation intended to prevent its disclosure to outsiders.\(^{327}\) Some of these measures such as bundling TMK with religious ceremonies might not be sufficient to restrict access to TMK by outside users, experts in the use of plants for bioprospecting may distinguish between a ceremonious procedure and one intended to extract healing elements.\(^{328}\) As a measure to effectively excluded outsiders, some indigenous groups refused to communicate their knowledge and ceremonies with outsiders.\(^{329}\)

If keeping TMK a trade secret is to be effective, knowledge holder communities would need to expend significant resources. Not all such communities will have such a capacity. Therefore, keeping TMK a secret does not seem to be a feasible route to encourage considerable investments in TMK codification and disclosure.

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\(^{326}\) Adamu, \textit{supra} note 57 at 54.

\(^{327}\) Carvalho, \textit{supra} note 3 at 245.

\(^{328}\) Ebermann, \textit{supra} note 110 at 129.

\(^{329}\) Carvalho, \textit{supra} note 3 at 245.
More important, however, keeping TMK a secret is not the welfare maximizing solution. Even if knowledge holders are successful in keeping TMK secret through social barriers, it does not guarantee its continued production, use, and dissemination. In fact, because of the pressures that continue to destroy the social, economic and environmental structures of knowledge holder communities, keeping TMK secret will only increase its rate of loss. Reports from ethnobotanical projects frequently state that, in many communities, only elders and traditional healers have access to TMK, and that when elders and traditional healers die, the knowledge dies with them. The fact that in many communities access to TMK is a privilege reserved for elders and traditional healers means that TMK will be lost forever if it is kept secret in the face of these socio-economic and environmental pressures disrupting the structures that support its sustained use.

Furthermore, most knowledge holders do not have the capacity to develop pharmaceutical products to meet national or global demand. It is possible to license a trade secret to firms that have the capacity to meet the demand for such products. However, licensing without any recognized rights over such secret is a risky proposition because of potential confusion with regard to the scope of the knowledge licensed and the lack of confidence that parties may feel in the absence of a legal backdrop. Negotiating over uncodified knowledge will also make it harder for parties to draft contracts. These risks might explain the lack of successful collaborations in this regard. The situation that knowledge holder communities find themselves in is in stark contrast to the potential of trade secrets for modern industries. Firms in such industries have the capacity to keep the knowledge secret while at the same time being able to commercialize it on a global scale.

**Government Provision**

Government provision is a major channel for the production of public goods in general and knowledge goods in particular. Many major studies and publications at universities, government agencies, and research institutes are publicly funded and contribute significantly to socio-economic development.\(^{330}\) Similarly, government supply or subsidy can supplement other means

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\(^{330}\) Additionally, governments set up prize systems in which quality research and publication is rewarded through a competitive process. Researchers, with the hope of receiving the financial reward and social recognition that comes
of supporting the codification and disclosure of TK. The codification attempts initiated by governments in some countries are good examples of this. The governments of India,\textsuperscript{331} China,\textsuperscript{332} South Korea,\textsuperscript{333} South Africa\textsuperscript{334} and Venezuela\textsuperscript{335} have invested significant amounts of financial and human resources to collect, organize, document and manage TK within their jurisdiction.

Despite the potential of government support, there are some issues that could limit government investment in the provision of TK.\textsuperscript{336} One major limitation is the fact that TK is a global public good that crosses borders easily. Knowledge that is supplied or subsidized by one government could be used by entities outside that country. Without a global system that recognizes such contributions, the producing country may be unable to control the uses of such knowledge.\textsuperscript{337} Discussing ‘Western’ knowledge production in general, the Nobel Prize-winning economist Joseph Stiglitz, argues that the global free-rider problem in which some countries will try to benefit by taking from the global pool of knowledge, rather than contributing to it is cause for concern.\textsuperscript{338} He states that a free-rider problem might limit the initiative of governments to fund global public goods, and posits that the establishment of a global entity that would manage

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\textsuperscript{331} Traditional Knowledge Digital Library (TKDL), supra note 159.
\textsuperscript{332} Yanling Sun, \textit{Introduction to China TCM Patent Database} (World Intellectual Property Organization, 2002).
\textsuperscript{336} Government investment in the provision of TK may include investments in infrastructure or in investing in the codification of TK itself.
\textsuperscript{337} In fact, the reason developing countries pushed for the signing of the Nagoya Protocol was the fact that they were unable to enforce access and benefit sharing requirements set out in their law against users in developed countries. See Wallbott, Wolff & Pozarowska, supra note 203 at 41.
\textsuperscript{338} Stiglitz, supra note 268 at 321.
\end{flushright}
investments in the production of knowledge might help optimize investments in global knowledge generation.\footnote{Ibid.}

This free-rider problem is particularly stark in the case of TK and genetic resources. While most TK and biodiversity resources are found in the global South, users of such knowledge are predominantly based in the global North where the necessary technological advancement and skill is found.\footnote{Wallbott, Wolff & Pozarowska, supra note 203 at 41.} Therefore, an investment by countries in the South for the codification of TK will face a significant free-rider problem because firms residing in countries of the North will be able to benefit from such codification without having to invest in it. In fact, this risk of free riders seems to be behind the restrictive measures taken by the TK codification initiatives in the TK provider countries noted earlier. These projects are oriented towards defensive protection (i.e. using the contents of the databases to stop others from claiming patent rights based on such knowledge).

Access to such databases is provided in a highly restricted manner to patent examiners for the sole purpose of use in patent examinations. Even the ‘open’ databases are limited to local uses within the community or the country. The potential global social welfare improvement that could result from the active use of TK, for instance in bioprospecting projects, is currently not being realized. These national endeavors to document TK are discussed in greater detail in Section 5.1 of the next chapter.

A collaborative initiative will be able to solve this inefficient state of affairs. It has been noted that the Global North benefits considerably from the continued availability of TK and biodiversity resources predominantly sourced from the Global South.\footnote{See generally, Nwabueze, supra note 323.} This fact should justify a requirement that the North invest in TK codification initiatives in the South in some form. Since the benefit that citizens of countries in the Global North receive from TK and biodiversity resources in the South is a diffused benefit, it is reasonable that the governments of the Global North should

\footnote{Traditional Knowledge Digital Library (TKDL) supra note 93 (India); “Traditional Chinese Medicine”, online: <http://www.sipo.gov.cn/> (China); “Traditional Chinese Medicine Patent Database”, online: <http://221.122.40.157/tcm_patent/englishversion/help/help.html>; Choi, supra note 332 (South Korea).}
support TK codification in the South. Furthermore, the North has far more capacity to subsidize the production and dissemination of TK than the South. Thus the real potential of TK is realized in situations where the North and South collaborate to bring together their comparative advantages to increase global access to TK. In the same way that production of ‘Western’ knowledge requires a global framework for optimal production and use, this challenge calls for a legal intervention at both the domestic and international levels.

Yet another limitation that could explain the failure of government provision of TK is the political and social tension that may exist between knowledge holder communities and the governments under which they exist. Although such tension exists in the case of many local communities, it is heightened in the case of enclave territories in which indigenous communities are usually marginalized by settler communities. As a result, proposals for government supply or subsidy of TK might be highly limited in some instances. In cases where TK holders trust foreign entities more than their governments, market provision might be more effective in encouraging investment in TK than government support. In the same way that government supply or subsidy is complemented by the market in ‘modern’ knowledge production, TK might need a complementary source. To sum up, although government investment in the infrastructure and substantive codification of TK may at times be promising, it faces considerable limitations that should be addressed through other channels.

**Group Cooperation**

As outlined above, norm-based systems such as the production of knowledge goods through group cooperation is another alternative channel for the production of the public good of knowledge. Norms, however, seem to require close communal relationships and repeated interactions in order to be effective. The examples discussed earlier in relation to norm-based intellectual property systems among chefs, and stand-up comedians work because of the close social ties

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344 Fauchart & Hippel, *supra* note 293.
members of such communities have. It could be claimed that the close social ties that have historically existed among members of knowledge holder communities created and sustained the norm-based regulations that worked for the use of TK within the community.

However, TK users do not have close ties with knowledge holder communities in the same way high-end chefs and stand-up comedians do with one another and with their audiences. Therefore, TK holder communities would not be able to use social sanctions on users in another part of the world. To use the Hoodia story described at the beginning of Chapter One, the San people of the Kalahari Desert would not be able to use social sanctions on firms that were involved in attempts to produce a pharmaceutical product from the Hoodia plant. The firms involved, Phytopharm, Pfizer, and Unilever, do not have close social ties with the San people, and there may not be repeated interactions between these stakeholders. Thus, the San would be unable to set up a successful social norm of access and benefit sharing with pharmaceutical firms, research institutions and the clients of such firms in distant locations. Because TK usually crosses political, cultural and economic boundaries, its regulation through group cooperation as used by chefs and other close-knit societies, is improbable.

Other Channels

Other alternative channels for the production of knowledge do not seem to be promising in the case of TK. For example, TK does not involve as high a cost of copying as in the case of technologically advanced knowledge. Therefore, the deterrence from copying that exists in advanced industries does not work in the case of TK. The first-mover advantage or lead time advantage that applies in advanced industries emanates from a breakthrough invention to which competitors do not yet have access. In the case of TK, because of its incremental nature, it seems unlikely that such channels would bring about sufficient commercial advantage.

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346 Ebermann, supra note 110 at 129.
Altruistic initiatives are yet another alternative. Charitable contributions for targeted initiatives could encourage the production and dissemination of TK to a certain extent. Thus, charitable contributions could be used with other methods of funding the codification and disclosure of TK. For example, a donation from a certain source could be matched by a government of a source country or a country in which a significant mass of users resides.

However, such an approach risks being a piecemeal solution that will not sufficiently address the problems on a global level. Successful initiatives that rely on charitable contributions seem to focus on particular issues that attract certain portions of the community which is concerned with a particular issue or seeks to contribute to solving a particular problem. For instance, individuals interested in improving access to education for young girls in developing countries would donate to projects in which the main direct beneficiaries are young girls in developing countries. Because the protection of TK might not be related to a narrowly defined issue of interest seen in other charitable causes, charitable contributions might produce limited funding insufficient for making significant change on a global scale. Despite these limitations, any avenue that could contribute to the establishment of an effective framework that encourages the codification and disclosure of TK, including charitable contributions, should be pursued. Major biopharmaceutical firms, for instance, could be interested in donating some financial and technical resources for particular areas or projects on TMK codification and disclosure. These contributions could supplement other measures intended to save TK from loss.

The fact that TK is at risk of destruction calls for innovative ways of addressing the problem. Although the market provision of TK will not be a panacea, it has great potential to supplement other channels that attempt to save the body of knowledge from destruction. Such attempts may range from crafting original schemes of protection to revisiting existing regimes. The next chapter provides one possible justification for the protection of TK.

As stated earlier, the core implication of labelling a resource as a public good is to help in forming a public policy judgment on how to ensure its production and use. Since each public good may have features that call for the adoption of a custom-fit regulation, sub-grouping resources might bring about more reflective regulations of the resource. Below is a discussion of the public
policy implications of labelling TK a public good and further defining it as an impure, uncodified, skill-embodied, and global public good.

3.2 Policy Implications

In most settings, national or international, society is required to prioritize investments in producing competing public goods. This process of prioritizing public goods involves comparing the inherent or strategic value of such goods. In the case of intellectual property protection, for instance, innovation seems to have been strategically prioritized over unhindered access to knowledge. In the case of TK, until recently, it was considered to be of less commercial value and therefore it was not prioritized as a public good worthy protection. This seems to be the case in most national jurisdictions of developed countries.

A similar prioritization can be observed internationally. Stiglitz has made a stark contrast between the lack of legal recognition for TK holders when their knowledge is used by firms in the Global north, and the ability of patent holders to receive all the rewards despite their invention having been built on pre-existing knowledge.347 His statement shows the North-South divide in international deliberations on TK protection.

One of the international discussions on TK is related to biodiversity resources on which TK depends. The politics of TK protection on the international stage is in part influenced by the location of megadiverse (biodiversity-rich) countries. ‘Megadiversity’ refers to the state of a locality in which it is host to a disproportionately high level of biological diversity. The uniqueness of a species to a certain country – endemism – is at the heart of the method used in

347 Stiglitz, supra note 267 at 316. Author states that “[t]he contrast could not be more stark between the way [TMK] is treated and the way adaptations of innovations in developing countries of patented ideas from developed countries are treated. In the first case all of the return is credited to the "discoverer" [patent holder], with none to the pre-existing knowledge. In the second case the patent holder is allowed to act as a perfectly discriminating monopolist, regardless of the extent to which his or her innovation built on pre-existing knowledge.”
determining which countries are megadiverse.\textsuperscript{348} The world’s biodiversity is not spread around the world equally; a disproportionate amount of the earth’s biodiversity is found in a few countries, and the tropical regions account for the lion’s share.

A major implication of grouping countries this way is to show the divide that exists between provider countries, which are mostly developing, and user countries, which are usually developed. Most megadiverse countries are developing countries in the global South\textsuperscript{349} while the financial and technological capacity to produce new products from such resources are found in the global North.\textsuperscript{350} This has triggered a North-South debate in which a country’s position as a net TK and biodiversity importer or exporter determines its stance on TK protection. Most developed countries which usually push for stronger protection of Intellectual Property (IP) rights object to strong protection for TK because they are net importers of such knowledge and biodiversity resources; while developing countries that usually object to stronger IP rights are proponents of increased TK protection because they are net exporters of TK and biodiversity resources. One can appreciate the political nature of IP and TK from the negotiation deadlocks in many forums including at WIPO.\textsuperscript{351}

\textsuperscript{348} See Biodiversity A-Z, \textit{Factsheet: Megadiverse Countries} (United Nations Environmental Program and World Conservation Monitoring Center, 2014) (‘Megadiversity’ is supplementary to other concepts such as biodiversity hotspots.) The seventeen countries labelled as megadiverse by the World Conservation Monitoring Center (which hold 70\% of the world’s biological diversity) and are: Australia, Brazil, China, Colombia, Democratic Republic of the Congo (DRC) (formerly Zaire), Ecuador, India, Indonesia, Madagascar, Malaysia, Mexico, Papua New Guinea, Peru, the Philippines, South Africa, the United States of America (USA) and Venezuela. The only official international group of megadiverse countries was formed on February 18, 2002 when some of the seventeen countries labelled as megadiverse announced the establishment of the Like-Minded Megadiverse Countries (LMMC) group. The group acts as a united front in international negotiations dealing with biodiversity and traditional knowledge in stages such as the CBD. See also text accompanying note 226.

\textsuperscript{349} The divide between these two groups is by no means a clear-cut. Some countries such as Australia, the United States, Brazil and India are at times both providers and users in that they are either developed countries or have developed the capacity to make advanced use of the biodiversity resources found in their jurisdictions. See \textit{ibid}.

\textsuperscript{350} See FN10 in, Oguamanam, \textit{supra} note 8 at 4.

\textsuperscript{351} The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has been deliberating on TK protection for over a decade. The work of the committee will be discussed in further detail under Chapter Five. “World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)”, online: <http://www.wipo.int/tk/en/igc/>.
Given the considerable evidence showing the value that TMK has inherently and as an input in bioprospecting projects, the low priority given to this body of knowledge should be revisited both nationally and internationally.\textsuperscript{352} There seems to be a promising trend in which some countries have recognized this need for reform and are legislating to protect TK. The international dialogue, however, has proved to be contentious, and negotiations have stalled. The different stakeholders involved and the dynamics of the international deliberation for TK protection are examined in detail in Chapter Five.

On a more theoretical level, the public policy tension in the case of the protection of TK is between users and providers of the knowledge. In the context of TMK, on the one hand there is the interest of pharmaceutical companies and research institutions (and ultimately consumers) who want unencumbered access to TMK. On the other hand, there is the interest of knowledge holder communities in benefiting from the knowledge they produce, use and, at least in some communities, keep secret. In this context, the difficulty legislators will face is in choosing what public good to prioritize and what scheme to adopt.\textsuperscript{353} Reliance on both utilitarian and equity-based judgments is advisable in order to choose one interest over the other or to craft a more nuanced system.\textsuperscript{354}

The continued provision of the knowledge is at risk because of the three core problems examined earlier in this chapter. This should make the case for the urgent and effective protection of TK. While indigenous and local communities produce and use TK in order to practice their own culture and lifestyle, they lack either the incentive to codify this valuable knowledge or to disclose it to outsiders. In fact, past experiences involving ‘misuse’ and ‘misappropriation’ of their knowledge have made them suspicious of outsiders and have encouraged them to keep their knowledge secret. The availability of TK will depend on a host of reasons, one of which is the incentive for

\textsuperscript{352} For a more detailed discussion of the value of TMK see section 1.2 under Chapter One. Farnsworth, supra note 235.
\textsuperscript{353} Taubman, supra note 4 at 547.
\textsuperscript{354} Ibid at 546.
knowledge providers to disclose it.\textsuperscript{355} Given the many examples in which knowledge holder communities restrict access to their TK for fear of losing control,\textsuperscript{356} it seems fair to assume that the greater the incentive available for knowledge holders the more they will be willing to codify and disclose their knowledge. Codification and disclosure, as argued in the next chapter, will externalize TK and make it accessible to users under certain conditions, thereby saving the body of knowledge from loss and under-use. If knowledge holder communities are facing extinction, their TK could at least be preserved for future use. The fact that the availability of TK depends on the willingness of providers to share\textsuperscript{357} pulls the public policy direction in favor of prioritizing the interest of knowledge providers. However, the competing interest of knowledge users for unhindered access should act to limit the rights of knowledge providers in such scheme.

Adding the equity element to this public good framework should tip the scale in favor of protecting TK. Equity justifications such as distributive justice\textsuperscript{358} and the general socio-economic inequality between knowledge providers and users suggest that the interest of indigenous peoples and local communities in benefiting from their knowledge should be given priority over the interest of knowledge users in having unencumbered access to such knowledge. These measures could, in turn, help bring about the global public good of more equitable economic and social development.\textsuperscript{359} However, beyond prioritizing between potentially conflicting interests, the continued use and sharing of TK does itself benefit users by being a source of continued input for products and services.

Furthermore, the most common argument against the protection of TK seems to be that it is knowledge already in the public domain. However, the concept of public domain in the sense

\begin{footnotes}
\item\textsuperscript{355} Other factors may include the factors such as the interest of knowledge holder communities to share their TMK, the availability of biodiversity resources to which TMK relates etc.
\item\textsuperscript{356} There are several examples where knowledge holder communities have been restricting access to their knowledge for fear of losing control over the knowledge once it is shared. For instance, see Saez, supra note 333.
\item\textsuperscript{357} Ebermann, supra note 110 at 130; Burk, supra note 239 at 1015 (Discussing generally the issue of tacit knowledge and how access to it dependent on the existence of the knowledge holding community).
\item\textsuperscript{358} A more detailed discussion of the equity based arguments for the protection of TK is provided in Section 2.1 under Chapter One
\item\textsuperscript{359} Carvalho, supra note 3 at 247; note 254 Preamble, para 5.
\end{footnotes}
commonly understood, as “material that is not covered by intellectual property rights,” is ‘Western’ in nature. A common way that knowledge becomes part of the public domain is when an intellectual property protection over such knowledge expires or when such protection is not extended in the first place. As discussed in Chapter One and throughout this dissertation, however, a considerable portion of TK has been disclosed by outsiders without the consent of knowledge holder communities and in violation of their customary laws. As rightly noted by Taubman, “TK did not “fall” into the public domain: it was pushed there, unjustly,” by disregarding customary laws of source communities. Therefore, the claim that TK should not be protected because it falls in the public domain is in many instances unjustified.

If the above discussed policy-based judgments on the need to create incentives are accepted, the next question is how much of an incentive is optimal. If a proposed mechanism is to be feasible and efficient, it should strike a balance between the interests of knowledge providers and those of users similarly to how IP laws balance conflicting interests of users and innovators. The incentive should be enough to encourage ‘optimal’ codification of TK while not extensive to the point of discouraging users from accessing it. Protection will encourage codification and disclosure, but if there is too much protection, it may discourage users, thereby making the system unworkable. Deciding on the optimal level of codification will not be easy and each jurisdiction will have to make that determination as a matter of public policy. However, a well planned mechanism with the goal of encouraging codification will be an improvement on current circumstances in which TK is being lost at an alarming rate.

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361 The term “public domain” has many variations depending on the context in which it is discussed. In the context of knowledge, ideas, and expressions, the public domain refers to knowledge which intellectual property laws either no longer protects or never protected in the first place, including spaces in which IP recognizes user rights over protected subject matter. The concept is most frequently used in the copyright context while the term “prior art” is the preferred term in patent law parlance. Both terms, however, refer to expression/knowledge to which no intellectual property obligation is attached. For a more detailed and enjoyable reading on the topic, see generally and on pages 38 - 39, ibid at 38–39.
362 Taubman, supra note 4 at 544.
363 Ibid at 544–45.
Additionally, it should be noted that the interest of both knowledge providers and users might be heterogeneous. While some knowledge providers may only want attribution, others may seek economic benefits. Similarly, users of TK range from institutions interested in conducting non-commercial research to pharmaceutical companies whose core interest is profit maximization. Any incentive mechanism should be designed with a capacity for addressing such diverse goals. For analysis of the diverse interests of TK users and providers in the context of TK codification, see Chapter Three, Section 3 and 4.

To generalize from the discussion in this section, categorizing TK as a public good with certain unique features should inform general policy judgments. The unique public good features of TK imply that the following key points should be considered for any policy that seeks to address the issue. First is the need for an urgent solution that could save TK from the alarming rate of loss that is faces.364 As stated at the beginning of this chapter, “knowledge of how to use…species is disappearing much faster than the species themselves…the knowledge that's being lost most rapidly is information on healing plants.”365 Research has revealed a range of 9% - 26% TK loss within the years between 2000 and 2009.366 A big part of the problem could be solved by encouraging the codification and disclosure of TK. The next chapter provides a detailed analysis of how legal intervention could encourage the codification and disclosure of TK.

While other measures such as building the capacity of knowledge holder communities to take legal and other actions is a commendable initiative, such measures are bound to take considerable time and would not address the problem in a timely fashion. Incentivizing codification through legal protection is, however, a feasible solution that could be implemented in a relatively short period of time. Once the knowledge is codified as a result of the legal intervention proposed in the next chapter, the legal protection will give knowledge holder communities the confidence to

364 Commentators have claimed that culture is being lost at a higher rate than biodiversity loss and thus faces a greater threat. Maffi, supra note 118; Correa, supra note 168 at 7; For the purposes of comparison, the Global Biodiversity Outlook 3, a report of the Secretariat of the Convention on Biological Diversity states that “[n]early a quarter of plant species are estimated to be threatened with extinction.” See, Global Biodiversity Outlook 3 (Montreal, Canada: Secretariat of the Convention on Biological Diversity, 2010) at 9.
365 Goleman, supra note 91.
366 Reyes-García et al, supra note 241.
share or license TK that they are interested in commercializing. The benefits received from codified and commercialized TK could be used in capacity building projects for knowledge holder communities that would address long-term concerns. Funds from the licensing of TK could, for instance, be used for poverty alleviation, capacity building, and biodiversity conservation. The Hoodia story provided at the beginning of Chapter One is a good example. The money received from the trust fund is invested in education and job creation for the San people of the Kalahari Desert, which may in turn help increase investment in the conservation of the knowledge and associated biodiversity resources.

The second general policy implication is that, given the global public good nature of TK, any proposed framework should address the effects of the extra-territorial application of TK. Mechanisms should be in place to address the negative impact that free-riding from users in other jurisdictions may have on a TK protection framework. This could take the form of an international mechanism which countries could adopt or domestic measures that could solve at least part of the problem.

A third policy implication is the need to strike the right balance between the needs and expectations of users and knowledge providers. If such a fragile system for the protection of TK is to be sustainable the interests of both sides should be reflected in the framework and rules. The incentive should be enough to encourage the ‘optimal’ codification of TK yet not be so extensive that it discourages users from accessing it. Protection will encourage codification and disclosure, but too much protection may discourage users, thereby making the system unworkable. Given the heterogeneity of stakeholders, the details of the rules that would satisfy the interest of knowledge holder communities and users may vary from one jurisdiction to another. However, some generalizations could be made. For instance, knowledge holder communities may be interested in a variety of remedies in addition to economic remedies, while users (especially firms) may give a high priority to the clarity of legal rules. While these general policy implications are useful in

367 It should be noted here that not all knowledge holder communities want to commercialize all of their TK. There may be sacred or secret knowledge that they would prefer to keep secret. Although such knowledge may not be commercialized, there is value in saving it from loss so that future generations of the knowledge holding community could make use of it.
framing a protection regime, a more detailed discussion of the interests of TK holders and users is provided in the next chapter under Section 3 and 4.

4 Conclusion

The dramatic rate of TK loss has been discussed in detail in this chapter. The three major causes of TK loss have been identified as the lack of codification, the destruction of TK holder communities and a rise in what is termed in this dissertation a ‘protectionist trend.’ Although there is some codification amongst indigenous peoples and local communities, oral transmission of knowledge is predominant, which results in the loss of TK when knowledge holders pass away. The destruction of the culture and biodiversity of TK holder communities are also key factors in disturbing the environment in which TK has been developed for generations. TK holder communities and megadiverse countries have become increasingly restrictive regarding access to their TK and biodiversity resources. This protectionist trend is a result of the lack of recognition of source communities and the absence of legal protection. The alarming rate of TK loss seems to be the result of a combined effect of these three features and is not exclusively attributable to any one of them.

The chapter then situates TK with other knowledge goods within the framework of non-rivalrous and non-excludable public goods to examine the deficiency of investment in addressing the lack of TK codification, and to explain the rise of the protectionist trend. The public goods literature discusses the unique feature of public goods and solutions that could address them. Thus, TK is described in general terms as an uncodified and impure global public good. The chapter has also explained the potential and limitations of alternative channels of production with regard to TK. Secrecy, government provision, and group cooperation are some of the channels of knowledge production examined.

Although some scholars have proposed the mechanism of trade secrecy as a potential model for TK protection, there are several factors that would make such a route challenging. TK holders’ lack of financial and technical know-how to keep their knowledge secret, the relative ease with which TK may be understood by outsiders, and the missed potential of a proactive use of TK for
welfare maximizing ends are some of the reasons that trade secrecy has limited potential as a framework. Government investment in TK codification endeavors is essential and some investment is already being made by megadiverse countries such as India, China, South Africa, South Korea and Venezuela. The significant global free-rider problem that could result in the case of TK and the tension between TK holder communities and their governments limit the potential of government investment in TK codification and disclosure. Despite such limitation, however, this chapter advocates TK codification projects in the South partly sponsored by governments of countries in the Global North. The potential of norm-based systems of knowledge production are also highly limited because the use of TK usually crosses cultural, economic and political boundaries, thereby making it hard to establish the social sanctions that make group cooperation work.

The purpose of categorizing TK as an uncodified and impure global public good is to help in the formulation of policy that reflects and responds to its unique features. Consequently, the key public policy points to focus on in the attempt to protect TK are: the fact that there is an urgent need to address the alarming rate of TK loss with a focus on TK codification; the need for global collaboration in order to address such global public goods; and the need to strike the right balance between the interests of knowledge providers and users to establish a sustained and efficient framework.
1. Introduction

At this point in the dissertation, it is fruitful to recall the distinction made between defensive and positive TK protection in chapter one. Defensive protection refers to attempts by TK holders and their advocates to stop outside users from claiming rights over knowledge based on TK. Defensive TK protection is less controversial than positive protection, and as discussed later in this chapter there are several initiatives that have been undertaken in this regard. This dissertation, however, focuses on the more contentious idea of positive TK protection, which refers to attempts to grant TK holders positive rights in their TK that would allow them to control how their TK is used by outsiders. The ‘incentive to codify’ argument posited in this chapter is therefore used to justify the need to create positive TK protection that encourages TK holders to codify and disclose their knowledge.

Building on the discussions of core problems causing TK loss and the public goods analysis provided in the previous chapter, this chapter argues that legal intervention designed to encourage TK holders to codify and disclose their TK is a key solution to save TK from loss. The chapter distinguishes TK codification from cultural conservation and calls for a shift towards the former as a core rationale for legal intervention.

The chapter then proceeds to discuss what form TK codification would take, and the benefits and limitations of codification. In order to help in framing TK codification attempts and the legal mechanism that would regulate such codification, the chapter examines the key interest of both TK holders and users. It is argued that a successful and sustainable TK codification should be reflective of these needs. The chapter concludes by analyzing national and international experiences regarding TK databases with the goal of examining the adequacy of such initiatives and in order to extract lessons that other similar initiatives could learn from existing TK codification attempts.
2 The Incentive to Codify

While indigenous and local communities produce and use TK to practice their culture and lifestyle, they lack the incentive for codifying this valuable knowledge and for disclosing it to outsiders. In fact, past experiences involving ‘misuse’ and ‘misappropriation’ of their knowledge have made them suspicious of outsiders and encouraged them to keep their knowledge secret. The lack of recognition and absence of an effective legal protection has also given rise to the protectionist trend discussed at the beginning of chapter two. The ‘incentive to codify’ argument proposes that a carefully crafted system that recognises and protects TK will encourage such communities to codify their knowledge and disclose it to outsiders. By codifying their knowledge, indigenous and local communities are increasing the public goods quality of TK – they are reducing the cost to others of copying it and making it easily accessible. If such transformation is to happen, the public goods literature suggests that knowledge providers would require a system that guarantees a level of control over what happens to their knowledge after it has been codified. If such a system is effectively executed, TK, in addition to possessing inherent value, will be an asset for research and development initiatives.

As described in chapter one, most of the scholarship on TK focuses on equity and distributive justice rationales and analyzes TK protection from a cultural conservation perspective. Although a minority, some scholars have discussed the value of documenting TK. Such scholarship, however, refers to the need to encourage codification only in passing and does not develop the proposal further. The strongest claim in this regard seems to have been made by Carvalho who posits that “[i]ntellectual property foreclosure of TK will have the undeniable benefit of generating an incentive to document and preserve it, thus protecting it from complete loss.” Carvalho then proceeds, without developing the argument further, to acknowledge that the benefit would depend on nature of the legal framework adopted. This section builds on the need for legal

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368 The lower the cost of copying the higher the appropriability problem of a public good, see Posner, supra note 289 at 66.
369 See for instance, Carvalho, supra note 3 at 100.
370 Ibid at 245 and at note 25.
intervention to address the disincentive TK holders have regarding codifying and disclosing their knowledge. It outlines the ‘incentive to codify’ rationale as a call for a shift in paradigm from focusing on cultural conservation to knowledge codification.

In addition to encouraging codification, legal intervention will address the worrying protectionist trend discussed in chapter two. Since the rise of this protectionist trend is caused by the lack of recognition and legal protection for TK, the establishment of a clear and balanced TK protection mechanism will give TK holders the confidence they need to make TK and genetic resources more accessible. Here, legal intervention works similarly to the way patent laws are used as an anti-secrecy tool. The incentive to disclose inventions is one of the key rationales for the creation of patent rights. The anticipation of exclusive right granted by such rights encourages inventors to document and disclose knowledge they would otherwise keep secret. Once disclosed, the knowledge could be easily commercialized, researched and built on. Similarly, the establishment of a TK protection mechanism could be expected to give TK holder communities the confidence to make TK more accessible, to commercialize it and to engage with others in its further use. It is hoped that the legal framework proposed in this dissertation will have a similar effect on the accessibility and use of TK.

### 2.1 Distinguishing Codification from Conservation

The goal of ‘conserving cultural heritage and identity’ predominates in the literature on TK protection. In the case of cultural practices, as opposed to biodiversity, one should be selective in what one seeks to keep. As the Princeton philosopher Kwame Anthony Appiah puts it, ‘preserving’ or ‘conserving’ culture is neither possible nor desirable. It is impossible because

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371 *Ibid* at 247.

372 See for instance, *Free World Trust v. Électro Santé Inc.*, [2000] S.C.J. No. 67, 2000 SCC 66, 2000 CSC 66, *supra* note 286 (Canada) ; *Eldred v Ashcroft*, 537 US 186 (2003), United States Supreme Court 186 at 244 (Stephen J. Dissenting: “Complete disclosure as a precondition to the issuance of a patent is part of the quid pro quo that justifies the limited monopoly for the inventor as a consideration for full and immediate access by the public when the limited time expires”).

373 Appiah, *supra* note 202 (Suggesting that cultures have always been mixing and so it is undesirable to attempt to keep them as pure as possible); For a shorter discussion of such claim, see Appiah, *supra* note 202.
cultures have been and will continue to be in a constant state of “contamination” (mixing) and, as a result, defining authentic culture is an ever elusive endeavour. Preservation could also be undesirable if it encourages traditional communities to continue practicing the same activities that keep them in a state of economic and social under-development that many members of the community may not accept. For example, preserving a culture in its ‘original’ or ‘static’ form as envisaged by many conservationists could also preserve harmful practices – an objective that may not be acceptable to at least some members of the community.

It may be tempting to take the position of a cultural purist. It seems reasonable to encourage historically disadvantaged cultures to be respected in the global cultural diffusion by providing some protection against dominant cultures. However, a general protection from any interference with a culture seems unreasonable. A more relevant point to the discussion at hand is that intellectual property type of protection is not the right tool for cultural conservation. It is a specific tool meant for the governance of the production, use, and dissemination of knowledge. The socio-economic and environmental pressures that cultures face should be addressed through other better-adapted measures. Additionally, strategic intervention with the goal of cultural preservation is a contentious issue and attempts to correct centuries of oppression. It will not be able to achieve its goals in the short term.

In contrast, embracing inevitable cultural diffusion lies at the heart of the codification argument. Cultures are in a process of continuous diffusion with one another, and thus codifying the knowledge that exists within a certain culture is necessary, not to keep the culture as it is, but so as not to lose knowledge that would otherwise disappear with the cultures that nurtured it. Appiah, who strongly rejects the preservationist position, agrees that codifying cultural artifacts is valuable for many purposes including for future study and personal enjoyment. It is proposed that such line of thought should be read expansively to include the codification of TK. By doing so, we allow cultural dialogue to take place while at the same time keeping useful knowledge in a way that allows it to be used by outsiders and future generations. Here, a cosmopolitan conception that

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374 Appiah, supra note 202.
375 Ibid.
encourages diversity and inter-cultural learning is adopted. The codification argument is a response to the alarming rate of TK loss discussed in chapter two.\textsuperscript{376} It proposes that codification of TK is the appropriate and most feasible response to create a consensus regarding TK protection. While other measures such as empowering knowledge holder communities and supporting them in socio-economic development activities are commendable, such initiatives are bound to take considerable time and cannot work in the short term to save the loss of TK. Incentivizing codification through legal protection is, however, a feasible solution that could be implemented in a relatively short time-frame.

Adopting an ‘incentive to codify’ justification brings new light to the debate surrounding the protection of TK and may thereby help create consensus. Although the incentive to codify justification seems similar to conservation arguments, there is a clear difference between them. Conservationists attempt to keep a certain culture and community as it is. Their main aim is preserving communities and cultures in their ‘authentic’ state. This conservationist approach may be a result of the fact that the movement for the protection of TK began as part of the movement for biodiversity conservation. As explained in chapter one, the Convention on Biodiversity was the first international treaty to expressly call for the protection of TK. It seems that conservationists erroneously adopted the same approach and wording in the protection of TK. The inevitability of cultural diffusion should be embraced, and instead, the focus should be directed towards saving TK from loss through codification.

Codifying the TK that exists in numerous communities around the globe will probably be costly. In addition to the costs related to documenting the knowledge, educating knowledge holders so they can take part in the administration of such system is necessary.\textsuperscript{377} The costs and challenges that come with codifying TK have played a role in its high rate of loss. If codified TK is recognized as valuable and given legal protection, it can result in a substantial flow of benefits from users to

\textsuperscript{376} Maffi, supra note 118 (Commenting that cultural and biodiversity loss exist and they both face pressure from the same sources); Correa, supra note 168 at 7 (Stating that culture is being lost at a higher rate than biodiversity and thus faced a greater threat); The Convention on the Protection and Promotion of the Diversity of Cultural Expression is a culmination of research and dialogue regarding the loss of cultural diversity. See Convention on the Protection and Promotion of the Diversity of Cultural Expressions, supra note 246.

\textsuperscript{377} The Crucible II Group, supra note 217 at 100.
knowledge providers. This sharing of wealth would enable TK holders to gradually be able to invest in TK codification and other supplementary measures such as educating community members. TK holders interested in commercializing their TK could enter into contractual relations with users in exchange for benefit sharing. In addition to encouraging codification, the recognition and legal protection of TK will serve the global public good of equitable development and help reduce income inequality. The resulting increase in value will incentivize many governments and communities to make the needed investment in TK with the intention of recouping such investment post-codification through commercialization. The focus here is codifying TK so as to sustain it, which is a necessary condition for its subsequent utilization.

2.2 Tacit versus Codified Knowledge

Beyond the debate on TK protection, there is a growing literature discussing the economics and management of knowledge in general. More specifically, the complex relationship between tacit and codified knowledge has attracted the attention of scholars from various fields. The concept of ‘tacit knowledge’ was first articulated by the Hungarian polymath Michael Polanyi in his famous 1966 book ‘The Tacit Dimension’. In his book, Polanyi argues that tacit knowledge, as opposed to codified knowledge, cannot be “put into exact words” but it is “a central feature of our knowledge of [the] world.” One of his central arguments is that knowledge cannot be codified to the exclusion of tacit knowledge. Several scholars have analyzed the concept of ‘tacit knowledge’ in diverse subject matters.

One such scholar is Dan Burk, who discusses the concept and its implication for patent laws. Burk classifies tacit knowledge into two: as the body of knowledge that is not codified because of the

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378 Bernard Ancori & Antoine Bureth, “The Economics of Knowledge: The Debate about Codification and Tacit Knowledge”.
380 Ibid Forward by Amartya Sen.
381 Ibid Forward by Amartya Sen.
high costs of codification; or because it is learned through observation or extensive experience.\textsuperscript{382} The second group includes the impossibility of codification because “some cognitive capacities resist explicit articulation” of the knowledge.\textsuperscript{383} There is growing literature on the balance that exists between tacit knowledge and codified knowledge and on how the two bodies of knowledge may exist hand in hand supporting one another.\textsuperscript{384} A cyclical relationship exists in that when knowledge is codified those who use the codified knowledge will, in turn, develop tacit knowledge through their own experience.

However, Burk further claims that patent laws shift the natural balance that exists between tacit knowledge and codified knowledge in that they encourage people to codify more of the tacit knowledge they own in order to benefit from the protection extended under the patent regime.\textsuperscript{385} As evidence of patent law’s push for the codification of tacit knowledge, he cites the disclosure requirement and the recognition of tacit knowledge as part of the prior art reference in the non-obviousness analysis under patent law.\textsuperscript{386} The codification of knowledge, or the “exteriorization of the memory” – results in knowledge that can be shared with and understood by others through simple observation or reading.\textsuperscript{387} Once knowledge is codified, it becomes durable and tangible, and can be easily commoditized and re-organized.

Burk considers further what the scope of codification should be. He argues that it is impossible to codify all tacit knowledge, and it is not even desirable to do so as there is a cyclical relationship between codified and tacit knowledge (i.e. once knowledge is codified, users will develop their

\textsuperscript{382} Burk, supra note 239 at 1014–15 (discussing the possibility that Tiger Woods may not be able to explain how he plays golf as an example of tacit knowledge).

\textsuperscript{383} Ibid at 1014.


\textsuperscript{385} Burk, supra note 239 at 1012.

\textsuperscript{386} Ibid at 1026.

\textsuperscript{387} Ibid at 1012.
own tacit knowledge). Since the purpose of codification is to save TK from loss and to enable further dissemination, the widest possible codification taking into account available resources is advocated for in this dissertation. As explained in the next chapter, a comprehensive TK codification provides more value by allowing researchers to use contextual knowledge to understand the information better. The codification should, in any case, allow users to understand the codified TK easily and to replicate, use or build on it in research. Codification should not be problematic since TK does not usually involve advanced technical elements.

Codification of TK will make it readily available for dissemination and commercialization. As Peter Drahos argues, “The degree of codification...affect[s] the public good qualities of information in important ways. Information that has been codified...may involve lower acquisition cost for potential users than other information.”

One of the core developments in the early 1840s that shaped current IP laws is the requirement for registration. Documentation seems to have been the result of necessity and utility, not something that was native to Western culture. The more comprehensively the codification of TK the greater its potential as an input in modern knowledge.

2.3 TK Codification

In the context of TK, codification is beneficial because, in addition to serving to increase social welfare by making the knowledge accessible, it will also renew interest among members of knowledge holder communities in continuing to practice their culture; codifying their TK and making it accessible. Codification will, however, also make it more of a public good than it would be by reducing its excludability – turning the uncodified and tacit TK into a codified body of knowledge. The more TK becomes a public good, the greater the risk related to non-excludability.

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388 Ibid at 1020.
389 Drahos, supra note 233 at 54.
390 Sherman, supra note 62 at 61.
391 More detailed discussion of the ‘incentives’ literature which claims generally that protecting TK will create a renewed interest in members of knowledge holder communities to continue practicing their culture is provided under Section 2.2.2 in Chapter one.
The public goods literature suggests that knowledge holder communities would not invest in codifying TK and making it publicly available without the promise of some benefit from such investment. An effective protection that reflects the needs and expectations of knowledge provider communities is indispensable if the goal of establishing collaborative and continued access to TK is adopted.

There are some ways in which TK databases could be utilized. They could be used for the simple purpose of codifying the knowledge for confidential local application only. They could be used defensively to invalidate non-inventive patents, or they could be used positively by actively licensing the knowledge and/or asserting rights in the content compiled in them.\footnote{392}{The Crucible II Group, \textit{supra} note 217 at 99.} While the confidential use of TK has value for its owners, its potential is not fully realized this way. The positive use of TK databases has considerable potential in maximizing social welfare. Such use is what is advocated in this thesis.

Scholars have argued that requiring the codification of TK for protection might be inefficient because over-investment or under-investment is a risk when it comes to traditional communities and indigenous groups.\footnote{393}{Munzer & Raustiala, \textit{supra} note 19 at 74; The Crucible II Group, \textit{supra} note 217 at 100.} Although risks of miscalculation in investment might exist, they may not be as frequent as sometimes claimed because codification is expected to be a comprehensive endeavor at a community or national level. Communities would codify as much TK as possible given the available resources, and some of the TK would, later on, prove to be of some value in producing a good or a service. As such the investment in TK codification and expected benefits are diffused. Concerning the potential of TK that is easy to commercialise, communities could work with public or private experts to value the TK and to make reasonable investments based on such value. The fact that indigenous and local communities can act as reasonable market actors has been shown in other contexts.\footnote{394}{Harold Demsetz, “Toward a Theory of Property Rights” (1967) 57:2 Am Econ Rev 347.}
The risks related to over-investment or under-valuation should not be sufficient reason to deter the establishment of a system of codification. There is still value in codifying tacit knowledge and making it available for dissemination. The financial gain from the protection of codified knowledge, no matter the amount, will help in sustaining TK. Although codification is not a panacea for all the problems that arise in TK production, it is one urgent solution that could address the core issue – the loss of TK and related genetic resources. This is not to say that codification is without shortcomings, but that its benefits outweigh its limitations. Below is a discussion of the benefits and limitations of codifying TK as a means of reducing or stopping TK loss.

2.4 Benefits of Codification

There are at least four important benefits to the codification of TK. Firstly, codification will help in the preservation of knowledge, thereby allowing its future utilization. This will have implications for the conservation of biodiversity in general and the promotion of TK systems in particular. Secondly, it will help in establishing a common ‘code’ for the communication of TK to different communities in the positive context discussed in the previous section. Thirdly, codification is indispensable to ascertaining the existence and scope of TK and information about the knowledge providing community. This will help establish certainty in the system. Lastly, the codification of TK and its ultimate protection is also useful in the evidentiary sense and in establishing the much-needed trust between indigenous peoples and outsiders – Western researchers, governments and multinational corporations in particular. These four benefits of codification are discussed in greater detail below.

TK codification will play an important role in preserving TK. As outlined in Chapter Two, there is extensive literature warning of the alarming rate of loss of TK. The International Institute

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395 Research revealed that the loss of TK related to the use of plants among Tsimane’ Amerindians (an Amazonian community) ranged “from 9% (for the female subsample) to 26% (for the subsample of people living close to towns).” See Victoria Reyes-García et al, “Evidence of Traditional Knowledge Loss Among a Contemporary Indigenous Society” (2013) 34:4 Evol Hum Behav Off J Hum Behav Evol Soc 249; For general recognition that TK faces a dramatic rate of loss, see Graham Dutfield, “Legal and Economic Aspects of Traditional Knowledge” in *Int Public Goods Transf Technol Glob Intellect Prop Regime* (Cambridge University Press, 2005) at 520; Carlos
for Environment and Development (IIED) reported that TK faces risks on several fronts. These risks include reduced interest among the younger generation, challenges to customary access to land and the prohibition of the practice of customary laws.\textsuperscript{396} TK loss may also be caused by the socio-economic development and integration which leads to abandonment of some cultural practices. While TK may at times be codified, it is mostly uncodified,\textsuperscript{397} which as stated earlier, causes an increased rate of TK loss. Furthermore, although traditional healers know that some plants have healing power if used in a particular way, they may not know why and how the plants have the effect they have. Close and continued cooperation between indigenous communities and companies, however, would result in the documentation of centuries’ worth of ‘trial and error’ data. Continued collaboration is important since the transfer of ‘tacit knowledge,’ i.e. knowledge that cannot be easily codified, may become essential for the research and development of TK. Such cooperation may also result in the use of the daily ‘research’ conducted by traditional healers leading to better and continued codification of ‘tacit knowledge.’ As rightly described by the Crucible Group, “Farmer’s fields and forests are laboratories. Farmers and healers are researchers. Every season is an experiment.”\textsuperscript{398} In addition to the contents of TK documentation, the dynamic and innovative practices of TK holders will be valuable for collaboration between ‘traditional’ and ‘modern’ knowledge systems in research and development projects.

Although some TK is ‘old’, it nonetheless includes a contemporary body of knowledge because of continuous processes of innovation. TK is held within communities and is transmitted from one generation to the other through informal means, and tacit knowledge that is held within communities will exist only as long as the communities continue to exist.\textsuperscript{399} Because of the tacit nature of most TK, the alarming rate at which it is being lost and the inevitable process of cultural diffusion, codifying TK becomes an urgent necessity. The ‘incentive to codify’ justification

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\textsuperscript{396} Maria Correa, \textit{Traditional Knowledge and Intellectual Property: Issues and options surrounding the protection of traditional knowledge - A discussion paper} (Quaker United Nations Office, 2001) at 7; International Institute for Environment and Development (IIED), \textit{Supra} note 33 at 5.

\textsuperscript{397} International Institute for Environment and Development (IIED), \textit{supra} note 34 at 5.

\textsuperscript{398} Correa, \textit{supra} note 168 at 7; International Institute for Environment and Development (IIED), \textit{supra} note 34 at 7.

\textsuperscript{399} People, plants and patents: the impact of intellectual property on biodiversity, conservation, trade, and rural society (Ottawa [Ont.]: International Development Research Centre, 1994) at xviii.

\textsuperscript{399} Burk, \textit{supra} note 239 at 1015.
\end{flushleft}
addresses the heart of the matter and may, therefore, create consensus among stakeholders. It may serve as an area of common agreement.

As discussed in the previous section, patent laws help establish a common ‘code’ through which invention in ‘modern’ societies can be documented.\textsuperscript{400} Such code is lacking in the case of TK, and, so, encouraging codification through protection will alleviate this problem. Having been considered to be of little or no value for a long time, TK has only recently been recognized by Western companies and governments for its potential as a source of knowledge.\textsuperscript{401} A major factor in this historical undervaluation is TK’s inaccessibility. There has been a lack of common ‘code’ – in terms of language and culture - through which indigenous and local communities could communicate their knowledge systems with outsiders. These cultural and linguistic barriers seem to have played a part in the delay in the diffusion of TK with modern knowledge system. Currently, increasing globalization has resulted in intercultural diffusion. It has become easier to recognize and understand the knowledge that other cultures hold and to consider its potential application to other situations. In the context of TK, this can be observed from the increasing number of therapeutic products that have been developed based on or inspired by TMK.\textsuperscript{402} The establishment of a common ‘code’ through which TK may be organized and communicated to the widest possible audience is, therefore, essential. Here, a patent-like standardized codification that describes the knowledge and its application in detail will be useful. As Burk observes, patent laws incentivize codification by recognizing the value in the documentation of the details of inventions and standardizing such systems.\textsuperscript{403} He goes even further to claim that the incentive that patent laws create for codification is more important than the original justification for patent rights\textsuperscript{404} i.e. as an incentive to encourage more inventions. Therefore, encouraging codification of TK

\begin{itemize}
\item \textsuperscript{400} See Section 2.2 above on the Codification of Knowledge. See also Burk, \textit{supra} note 239.
\item \textsuperscript{401} Dutfield, \textit{supra} note 59 at 504 (Dedicating a section to discuss the economic value of TMK).
\item \textsuperscript{402} For example, the South Korean patent office has documented an increasing number of traditional South Korean medicinal knowledge based patents. See Choi, \textit{supra} note 333 at 3 & 6; There seems to also be an increasing number of research showing the potential of TMK for the production of effective modern medicine. For example, see Saslis-Lagoudakis et al, \textit{supra} note 100; See also, Fabricant & Farnsworth, \textit{supra} note 96.
\item \textsuperscript{403} Burk, \textit{supra} note 239 at 1011.
\item \textsuperscript{404} \textit{Ibid} at 1012 (The quid pro quo theory of justifying patents refers to the benefit the general public gets from increased inventions that are incentivized by the short term exclusive rights given to inventors).
\end{itemize}
through a common ‘code’ recognized and valued by a protection mechanism may result in increasing codification of TK and its sustainable existence outside a given community or personal memory.

Still another main benefit of codification is its ability to create certainty in a system filled with misunderstandings. The certainty that databases bring includes issues such as the existence of the knowledge, its content and scope.\(^{405}\) This is especially important given the nature of TK. As discussed in previous sections, TK is know-how and therefore resembles inventions protected under patents, a system in which documentation and registration play a key part. In contrast, TK is mostly uncodified and this affects its ability to be protected and widely used. The uncertainty in TK protection has created transaction costs that make it hard for companies to do business.\(^{406}\) Hence, TK databases seem indispensable for establishing an effective system of protection whether the interest of TK holders is to simply codify TK or to further commercialize it by engaging with users.

TK databases also have notice and evidentiary benefits. In the absence of a registered TK, users will not know who owns what and knowledge holder communities would have the burden of proving that the knowledge originated with them or that the user accessed it without their consent.\(^{407}\) If knowledge is already registered, registration can be taken as a prima facie evidence of ownership and the user would have the burden to prove otherwise. The sophisticated systems of writings, publications, and citations in ‘modern’ knowledge management allow for proper attribution. The absence of such systems in the traditional knowledge management contributes significantly to the lack of proper attribution. Codification will solve this problem. An added advantage of databases would be their ability to be used defensively. Codification would support

\(^{405}\) Carvalho, supra note 3 at 261; The Crucible II Group, supra note 217 at 100.
\(^{406}\) Wallbott, Wolff & Pozarowska, supra note 203 at 41; Carvalho, supra note 3 at 246.
\(^{407}\) The Crucible II Group, supra note 217 at 100.
patent examiners in their effort to stop biopiracy\textsuperscript{408} by allowing them to reject non-inventive patent applications based on TK. There are several examples of TK databases being used effectively to invalidate non-inventive patents.\textsuperscript{409}

In order for a diffusion of TK and ‘modern’ knowledge to take place, indigenous people have to trust outsiders before sharing their knowledge with them. As things stand, because of differences in ideological approaches and past negative experiences, indigenous groups are suspicious of outsiders. A clear and effective codification and protection mechanism for TK has the potential to build the confidence of TK holder communities to engage in a relationship with outsiders on a more balanced basis.

### 2.5 Limitations of Codification

Undeniably, codifying TK has its limitations. Critics of TK databases give several reasons for opposing codification. While most of these reasons arise from practical concerns, others are based on principles. Even if there are strong arguments against codifying TK, rather than calling for the outright rejection of codification entirely, they call for care in the process of codification and nuances in their regulation. One major criticism is the fact that codification based on commercial value will disregard TK that is not ready for commercialization. Therefore such criticism is dealt with separately first. Following that, other criticisms are discussed.

\textsuperscript{408} As defined in chapter one, ‘Biopiracy’ is a term used to describe situations in which patent rights (or other intellectual property rights) are granted over an invention or an expression that is based on a TK (broadly defined) without compensating the source community or country.

\textsuperscript{409} For a discussion of examples of TK databases being used in patent persecution procedures, see Section 5, National and International Experiences.
2.5.1 Risk of Disregarding ‘Non-commercial’ TK

One criticism of encouraging codification through economic benefits is that the codification will exclusively focus on knowledge that is readily applicable at the expense of knowledge that is not readily applicable or knowledge for which the current value is unknown. The argument is a strong one, especially since similar occurrences are seen in other areas such as the pharmaceutical industry which has failed to address ‘neglected disease’.\textsuperscript{410} Commercialization is a large part of the ‘incentive to codify’ justification in that the expected gain from commercialization is expected to encourage codification of TK. As such, the above criticism applies in this context. However, a number of counter-arguments limit the extent of this criticism.

First, economic benefits will encourage the codification of all TK because it is hard for knowledge holders to estimate \textit{ex-ante} whether a certain element of knowledge will be valuable. As such, the incentive of economic benefit could be expected to be a diffused one in that it will encourage knowledge holders to codify as much knowledge as possible. Even if knowledge providers are able to distinguish between commercially valuable knowledge and abstract knowledge, the benefits they receive from commercialized knowledge has the potential to create an increased interest in continuing the practice of their culture, albeit in an ever-evolving manner. If communities are interested in codifying TK that does not have commercial value, the economic gains from commercialized TK would give them the capacity to invest in codifying non-commercial TK. It is acknowledged that the receipt of economic benefits may change the culture of TK holders. However, as long as their TK is codified, even if TK holder communities’ culture changes because of new found economic benefits, the knowledge will continue to exist for use by future generations of the same community or for outsiders.

Most importantly, the criticism calls for innovation in the regulation of TK codification and is not a basis for rejecting the ‘incentive to codify’ argument altogether. One innovative way of addressing the concern is to examine the way ‘modern’ knowledge production takes place. Public

funding is used to encourage the production of basic science in Western societies while private investments are mostly made in applied science. A good example is innovation that takes place in publicly funded universities which is later on acquired by firms for further development and marketing. As such, the initial support for codification of TK, such as educating communities and establishing the infrastructure, could come from public sources. Once codified knowledge is available, the possible benefits from this knowledge could be used to cover the cost of codifying TK that may not have a clear commercial value.

The impressive codification and dissemination of modern knowledge was made possible, in part, because of incentives provided to those who produced or owned it. These range from strictly financial incentives to promotions and social recognition, and cover the production of commercially applicable knowledge as well as abstract knowledge. TK databases could similarly codify as much knowledge as possible using available technological advancements such as digital and multi-media technologies. Once the initial public investment has been made, the market will decide what is commercially valuable and what is not. The costs related to codification of TK that is not readily applicable may be covered through public sources and through re-use of benefits from applied TK. Moreover, if the alternative to codification is loss, then it is better to codify some TK than lose it all.

2.5.2 Other Major Limitations

Critics argue that it is impossible to codify every TK that a community holds.411 This is sometimes supplemented with the argument that not all TK can be expressed in a fixed form.412 It is true that codifying knowledge is not an easy task. However, as outlined in earlier sections,413 although a comprehensive codification is preferred, not all of the knowledge a community holds needs to be codified. What is required is enough content for users to understand and build on. It is true that some TK holders may be unable to explain their knowledge in the same way inventors applying

411 The Crucible II Group, supra note 217 at 100.
412 Oguamanam, supra note 8 at 151.
413 See section 2.3 on TK Codification
for patent rights can. In such cases, explaining the procedures that TK holder communities follow should be sufficient. A pharmaceutical company that seeks to conduct bioprospecting projects may be satisfied with having access to the plant used in treating a disease and the method of extracting elements and administering the treatment. Hence, as long as there is enough information in the database to allow a researcher to understand these elements of TK, the database has served its purpose. In order for the proposed system to work, a relatively low level of detail should be sufficient for protection. Patent registers hold important lessons for the development of TK databases, although some of the unique features of TK call for careful adaptation. In general, some degree of codification is better than the current situation which is predominated by uncodified TK.

The effect that databases have in disclosing TK to outsiders is seen as another reason to oppose codification. Knowledge holders have justly been hesitant to document their knowledge, fearing that it will result in biopiracy. A carefully crafted TK database in which the scope of TK ownership of knowledge holders is clearly outlined would allay such concerns. Codification will facilitate collaboration between knowledge providers and users, and it will address the power imbalance in the status quo by clearly outlining the rights and obligations of parties. The appropriate response is not to reject codification in its entirety but to create databases acceptable to both sides. One solution is to keep the database confidential and use it for evidentiary purposes only. Confidential databases have the capacity to prevent TK loss while allowing knowledge holders to prove the existence, scope and ownership of TK. However, as stated earlier, defensive uses of codified TK misses the potential welfare-maximizing ability of positive and collaborative use. Critics also argue that establishing a TK database will give those who want to use uncodified TK a defense in claiming lack of community ownership of uncodified TK. In such cases regulatory flexibility is required in that evidence of ownership or existence of TK should be

414 Carvalho, supra note 3 at 260.
415 Ibid at 248.
416 The Crucible II Group, supra note 217 at 101.
417 Ibid.
admitted in the absence of codification if there is a strong evidence that the user misled or misinformed TK holders in order to gain access to TK.

The disruptive effect that codification of TK might have on cultures is used as a basis for objecting to the development of databases. For instance, it is argued that fixation will disintegrate the oral tradition that dominated the development of TK over the centuries.  

Although it is true that most TK is transmitted orally, its codification will not stop knowledge holders from continuing to practice their culture in the same manner. The documented TK could be used strictly for outside purposes if that is the wish of the particular knowledge holder community. It is also maintained that codifying TK might not reflect its holistic and dynamic nature or that it will “translocate” it from its origins. However, it is possible, through the use of technological advancements, to create databases that could document TK with its dynamic features. The TK databases discussed under Section 5.1 are good examples of databases capable of respecting the cultural contexts of TK. Attribution may be an additional concern, but, it is possible to require that the origin of the knowledge be explicitly stated in databases and on disseminated documents. The practice of attribution is not foreign: it exists in other areas of ‘modern’ societies such as with citations in academic publications. Therefore, such practice could be adapted in the context of TK use.

Yet another criticism within the cultural disruption school is that increased contact with communities that have been secluded for centuries may destroy their ‘pure’ culture. The Brazilian government, for instance, has taken the stance that one ‘uncontacted’ tribe in the Amazon should be left uncontacted because of the fear that the community could be affected by outside cultures. It is acknowledged that there may be some costs associated with contacting such communities including the risk of spreading foreign diseases. However, as discussed at the beginning of this chapter, attempts to keep cultures in an authentic form may be impossible.

418 Oguamanam, supra note 8 at 151.
419 Ibid.
420 See generally, Carvalho, supra note 3.
421 The fear that the community members could be infected with a disease foreign to them was also part of the reason for the government's decision. See for instance, Face to face with isolated Amazon tribe in Brazil.
Despite the Brazilian government’s decision not to contact the tribe, the community seems to have had some contact with neighboring communities and is under a threat of extinction because of illegal logging.\textsuperscript{422} If such community becomes extinct, in addition to the destruction of the community, knowledge of their way of life including TK will disappear with them — an undesirable outcome for both the community and the global public.

Another argument against databases cites the prohibitive financial resources required to create and manage them. In addition to the costs referred to earlier, critics state that educating and collaborating with knowledge holders as a community may be required so that community members could easily participate in the codification attempt; and such initiative will result in substantial costs.\textsuperscript{423} It is true that codifying and sustaining knowledge in a TK database requires substantial investment. However, instead of being an argument against codification, it is a rationale for the need to codify knowledge and calls for innovation in financing the construction and management of database. Public grants, loans or income generated from initial licensing of TK could cover such costs. Concerns related to language translation exist\textsuperscript{424} but these could be addressed through language and cultural experts, as needed.

Another criticism of codification may be that codifying TK will simply translate it into another knowledge system – the Western knowledge system. This, however, is incorrect. Transcribing knowledge into written form is not an inherently Western concept. Many ancient communities documented part of their knowledge including in rock paintings, and later on in papyrus, books, and other writing media. Using advancements in communications tools, including in the digital technology realm, translating TK into a systematically structured documentation could still keep the knowledge in the form is it developed. The only change would be that is documented in some form for posterity.

\textsuperscript{422} For instance, the Brazilian government has stated that the uncontacted communities had tools that suggest they have been in contact with other remote communities. See \textit{ibid}.
\textsuperscript{423} Oguamanam, \textit{supra} note 8 at 151; The Crucible II Group, \textit{supra} note 217 at 100.
\textsuperscript{424} Oguamanam, \textit{supra} note 8 at 151.
Overall, the several concerns related to the codification of TK could be overcome through a database that makes full use of technological advancements; and is dynamic enough to accommodate cultural differences, improvements and special features of TK. The Traditional Knowledge Digital Library (TKDL) in India may be a good example because it has a dynamic feature in that the 35,000 formulations that it hosts can be updated periodically. Since the benefits of codification seem to outweigh the limitations, rather than categorically objecting to codification scholars should explore innovative systems that could alleviate the concerns.

In order to craft a successful and reflective TK database it is necessary to examine the interests of both knowledge providers and user. Inclusion of stakeholders at various stages of the process will instill a feeling of ownership on both sides, leading to a successful system. Below is a discussion of the interests that knowledge providers and users might have in TK databases.

3 Interest of TK Holders

Until recently, traditional knowledge was considered to be freely accessible to outsiders. There are instances of researchers disclosing TK without the consent of knowledge holders. As a result, some of this TK is currently publicly disseminated. This does not mean that knowledge holders did not have any norms that protected TK. In fact, indigenous and local communities view TK in diverse ways with some norms requiring property-like treatment and others adopting open access approaches. The framework under which codified TK is to be protected should reflect this diversity of interests and expectations.

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425 For more on the Traditional Knowledge Digital Library see Section 5.1 National Experiences below. See also V K Gupta, Presentation on Traditional Knowledge Digital Library at the Third Session of the Inter-Governmental Committee, World Intellectual Property Organization (World Intellectual Property Office, 2002) at 10.

426 Reichman & Lewis, supra note 5 at 345.
As discussed in Chapter One, TK holders might have diverse interests and world views. However, there are principles and values that most of them share.\textsuperscript{427} These include a ‘\textit{holistic worldview}’ that considers human beings to be part of an interconnected web of relationships and responsibilities; and ‘\textit{Spiritual beliefs}’ in that everything – ‘living’ or ‘non-living’ - should be honored.\textsuperscript{428} TK databases can be crafted to allow TK holders to categorize spiritually sensitive TK so that it can be used in a way that will not offend TK holders or for such TK to not be registered at all.\textsuperscript{429} It is also possible to exclude culturally and spiritually sensitive TK. Additionally, databases could be made to include the cultural context in which TK is developed.

The values of ‘\textit{reciprocity}’ and ‘\textit{equilibrium}’ in the relationship between society and nature and that of ‘\textit{duality}’ (the understanding that different perspectives and ways of knowing could be used complementarily) have been identified as common elements shared by most, if not all, TK holders.\textsuperscript{430} The shared value of \textit{duality} could be useful in establishing a pluralistic protection regime that mixes traditional and Western understandings, while the principle of \textit{reciprocity}\textsuperscript{431} could be looked at when crafting a system of benefit-sharing based on both monetary and non-monetary benefit sharing. Even if these values are abstract in nature this level of generality is required in order to leave space for each local community to include their unique customary values and principles.

TK access granted under a ‘terms and conditions’ type of requirement is another feature that is shared by most knowledge holder communities. This may include conditions on access and use of knowledge, time limits and revocation of consent upon misuse.\textsuperscript{432} While traditional

\textsuperscript{427} World Intellectual Property Organization, \textit{supra} note 27; Barsh, \textit{supra} note 56 at 73–75; International Institute for Environment and Development (IIED), \textit{supra} note 34 at 5.

\textsuperscript{428} International Institute for Environment and Development (IIED), \textit{supra} note 34 at 5.


\textsuperscript{430} International Institute for Environment and Development (IIED), \textit{supra} note 34 at 5.

\textsuperscript{431} Barsh, \textit{supra} note 55 at 75 (Commenting that the principle of reciprocity and generosity are useful in benefit sharing discussions).

\textsuperscript{432} \textit{Ibid} at 74.
communities have a culture of open sharing when it comes to some aspects of their TK, there are areas where they keep their knowledge restricted. The secret use of knowledge may be for spiritual reasons, to safeguard knowledge from outsiders or to prevent knowledge from falling into the hands of uninitiated community members. TMK tends to be kept secret with only healers and elders having access to it. As outlined in the first chapter, the interest of TK holders may be categorized into defensive and positive protection. In defensive protection, TK holders can oppose misuse of their knowledge by outsiders, while with positive protection they might go as far as controlling who uses TK, in what way, and the benefits to be shared with them. If a knowledge holder community has customary norms in this regard, effort should be made to craft a system that works with such norms. Such an attempt may foster a spirit of collaboration and trust.

In addition to the general expectations of knowledge providers, more practical needs in setting up TK codification can be observed from statements of government officials. In this context, one major need of knowledge providers is the building of the capacity of indigenous and local communities to manage databases. The precise form of assistance might depend on the goals of the requesting community. For instance, the draft TK database toolkit which has been developed by WIPO and is being used by knowledge holder communities may be essential for a community lacking government support. Another practical aspect is in negotiating and controlling the IP implications of codifying their knowledge. If codifying their TK means putting it in the public domain and the loss of rights over such knowledge, communities will be discouraged from investing in codification. This disincentive is a key point made in the public good analysis of TK. A third expectation is the “security and confidentiality of information compiled in databases.”

Codifying TK will result in making it more accessible to outsiders who

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433 Ibid.
434 Inventory of existing online databases containing traditional knowledge documentation data, supra note 236 at para 96.
436 Inventory of existing online databases containing traditional knowledge documentation data, supra note 236 at para 100-101.
437 Ibid at para 101.
are not governed by the norms of knowledge providing communities. Therefore, some knowledge providers may want a guarantee that, once codified, their knowledge is secure and kept confidential.

Since traditional communities are at the heart of the discussion regarding the protection of TK, space should be made for effective inclusion and dialogue between knowledge providers, users and governments. The past practice of forcing indigenous and local communities to accept Western systems and their limitations might result in refusal to cooperate. Effective inclusion can reasonably be expected to result in a feeling of ownership and trust on the part of knowledge providers. Codification of knowledge would mean making a skill-embodied uncodified knowledge more easily accessible to outsiders – which may be against the practice of some groups. Even in the case of confidentially codified TK, the documentation of the knowledge would make it more accessible if the TK holding community licenses such knowledge under confidential terms or decides to make it public at a later point. The trust of knowledge providers in a system designed to benefit them is, therefore, a key factor if codification and dissemination is to be successful. A system over which such communities will have control post-codification will help establish such trust.

4 Interest of Users

The interest of users of TK databases should also be considered in codification attempts, at least if the objective of the codification is to disseminate and use the knowledge outside the originating community. Although confidential databases which are created for the sole benefit of the local community are an option and can prevent the loss of TK, the value of such databases would be highly limited. Provided that the fears of knowledge providers are alleviated, disseminating knowledge to outsiders may be consistent with the values of “[g]enerosity and reciprocity” shared by many communities.

438 Barsh, supra note 56 at 75.
439 Ibid (Commenting that the principle of reciprocity and Generosity are useful in benefit sharing discussions).
Here it should be noted that users of TK are diverse in terms of background and interest. They include firms such as pharmaceutical and biotechnology companies expecting to develop a commercially viable drug or treatment; universities, governmental and non-governmental organization and research institutions interested in non-commercial exploitation and dissemination of TK; modern commercial entities that seek to use TK as is, without conducting additional R & D; and individuals seeking to use TK for personal therapy. Listing all of the interests and expectations of such a diverse group of users is difficult. However, general observations can be made about them. It has been argued that the position of industry, presumed by many to be against the protection of TK, has not been strongly for or against it. However, current practices favor industry which is able to use TK without sharing benefits. This status quo could explain the relative silence from the industry. Also, this may be as a result of a strategic decision to avoid public backlash and/or a belief that current proposals for TK protection will not change the state of affairs. That said, some responses exist from which the position of the industry can be deduced. For instance, the position of developed country governments is generally against the establishment of a protection mechanism for TK. This position of developed countries in which major firms that use TK are based is telling of industry’s view. It has been pointed out that some industry leaders have lobbied their governments into taking positions against expansive protection of TK.

Certainty and reliability in the database; the type of TK protection regime; and in the type of benefit sharing mechanisms are at the core of what users seem to be concerned about. These expectations are related to a number of concerns users may have. Ambiguity relating to what is protected and how to determine the rights and obligations involved will frustrate companies and

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440 As stated under Chapter One, the term “users” is used to refer to a diverse group of “individuals or entities that actually import and utilize genetic resources whether for commercial or purely scientific purpose,” Charles Victor Barber, Sam Johnston & Brendan Tobin, Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity (2nd edition) - United Nations University (United Nations University, 2003) at 20.
441 Ibid.
442 Roberts, supra note 151.
researchers who plan to make considerable investments in acquiring and using TK.\textsuperscript{444} Since the protection of TK is an exception to the general rule of making knowledge freely accessible, the content and scope of the limitation should be defensible.\textsuperscript{445} This is especially important for the ‘unpredictable arts’ (as opposed to the applied arts) which refers to fields in chemistry and biology such as pharmacology and biotechnology which involve significant risk of failure.\textsuperscript{446} Uncertainty in using TK in such fields might increase their risks even further and make bioprospecting projects unfeasible. This may, in turn, force them to use less efficient alternatives for R & D in drug discovery. There have been several negative experiences in which the public reputation of companies involved in biopiracy and/or unsuccessful access and benefit sharing agreements has been damaging.\textsuperscript{447} Research institutes may also fear legal claims arising from such uncertainties and shy away from the use of TK in their research.\textsuperscript{448}

Furthermore, if the uncertainty and scope of TK protection result in significant restrictions on current IP rights, a powerful industry lobby may begin to pressure governments against the protection of TK.\textsuperscript{449} This does not mean that TK protection should never interfere with the current status quo — such interference might be necessary — but care should be taken to ensure that the disruption is justified and reasonable. There is risk when several systems of protection attempt to

\textsuperscript{444} Ibid; Roberts, supra note 151.
\textsuperscript{445} Roberts, supra note 151.
\textsuperscript{446} The unpredictable arts, as opposed to the applied arts, refer to fields in chemistry and biology such as pharmacology and biotechnology which involve significant risk of failure. The unpredictability may arise from the natural uncertainty in chemical and biological reactions, the newness of the field or lengthy regulatory procedures. See Section 2164.03 - Manual of Patent Examining Procedure: Relationship of Predictability of the Art and the Enablmenet Requirement (United States Patents and Trademarks Office, 2014); For a discussion of case law in the area of the unpredictable arts, see Sean B Seymore, “Heightened Enablement in the Unpredictable Arts” (2008) 56 UCLA Law Rev 127.
\textsuperscript{447} The uproar that resulted when companies applied for patent rights over genetic resources and traditional knowledge used by indigenous and local communities could reasonably be expected to result in some damage to the reputation of firms involved. The most famous cases of biosquatting include the neem tree, basmati rice, the hoodia plant, turmeric, the rosie periwinkle plant, the ayahuasca plant and knowledge of their use. For example, for the Rosie Periwinkle case, see Osseo-Asare, supra note 1 at 31; For the neem tree case, see Vandana Shiva & Radha Holla-Bhar, “Piracy by Patent: The Case of the Neem Tree” in Jerry Mander & Edward Goldsmith, eds, Case Glob Econ Turn Local (San Francisco: Sierra Club Books, 1996).
\textsuperscript{449} Roberts, supra note 151.
cover the same subject matter. If too many actors have rights over final products (eg. drugs) overlapping rights may result in the anti-commons scenario\(^{450}\) that could discourage collaborative R & D. TK codification, although not a panacea, has the potential to create confidence among users who would have an accessible source to consult regarding the existence and ownership of TK.

Accessibility may be another major expectation of users.\(^{451}\) If much red tape exists in accessing TK and related genetic resources users will be reluctant to invest in the area.\(^{452}\) This calls for the use of sophisticated collection, organization and dissemination systems to help users from different backgrounds access TK easily.\(^{453}\) There have been some concerns regarding proposals that benefit sharing promises be made before the potential of the knowledge and genetic resource is analyzed.\(^{454}\) This \textit{ex ante} requirement to negotiate adds to the risk of developing a marketable product and might push users away from TK. It is possible to negotiate a percentage-based license rather than a specific sum of money. However, calculating the share of benefits providers deserve is no easy task.\(^{455}\) Consequently, the development of protection mechanisms should involve user stakeholders in order to craft an accessible system that works for all parties. The system might, alienate users and may not achieve its goal of positive use of TK.

\(^{450}\) The concept of the anti-commons refers to a situation when too many parties have exclusionary rights in a resource leading to its underuse. This is contrasted to the tragedy of the commons in which parties that have the right to use a common resource end up overusing it. The concept of anti-commons was first explored by Michael Heller in 1998. See generally, Michael A Heller, “The Tragedy of the Anticommons: Property in the Transition from Marx to Markets, The” (1997) 111 Harv Law Rev 621.

\(^{451}\) For example, developed countries pressured by industries in their jurisdiction have negotiated for the establishment of a clear and accessible system for the access and benefit sharing mechanisms in developing countries in the Nagoya Protocol negotiations. See Wallbott, Wolff & Pozarowska, \textit{supra} note 203 at 38–39.

\(^{452}\) Intellectual Property Institute of Canada, \textit{supra} note 448 at 2 (Copy with author).

\(^{453}\) \textit{Inventory of existing online databases containing traditional knowledge documentation data, supra} note 236 at 32–33 (listing accessibility issues such as classification, search tools, dictionaries and thesauri as being the needs of users in TK databases).

\(^{454}\) Intellectual Property Institute of Canada, \textit{supra} note 448 at 2.

\(^{455}\) \textit{Ibid}.
Yet another related concern is the remedy in case of infringement. Inadvertent infringement is a major concern for users as is what remedy knowledge holders might be granted. This results in restricting the cost-benefit analysis that users might plan to conduct before being involved in TK-related projects. Protection mechanisms should also have different rules for different types of use. Potential classifications are individuals, entities with non-commercial interests and entities with commercial interests. Access to and benefit sharing of TK and genetic resource could be adopted based on such a system.

The previous sections have outlined the need for legal intervention to encourage TK codification; and they have distinguished what is meant by TK codification from cultural preservation. The benefits and limitations of TK codification and the interest of TK holders and user have also been examined. Now, it may be fruitful to analyze the potential and challenges of existing TK codification initiatives to evaluate whether they are efficient and what, if any, improvements may be advisable. Analysis of the national and international initiatives to codify TK is also provided as examples of ways in which government investment could help start the process of TK codification which can later on be supported by other channels including through market mechanisms.

5 National and International Experiences

While the debate about the protection of TK is underway, some national governments have started codifying TK found within their jurisdictions. Even if these are recent experiences, they provide important lessons for the development and use of TK codification. There has not yet been any holistic international TK database. However, the work of the WIPO and the United Nations Convention to Combat Desertification (UNCCD) in supporting national databases is worth noting. A discussion of sample national experiences will be followed by a brief outline of international initiatives.

\[\text{Ibid.} \]
5.1. National Experiences

While some countries have already established a TK database, still others are working towards creating such a system.\(^{457}\) A detailed discussion of each is beyond the scope of this thesis. A brief discussion of the most robust projects may, however, reveal the potential and limitations of TK codification. The TK database initiatives in India, China, South Korea, South Africa and Venezuela are all worth noting in this regard. A general discussion of how these countries have handled codification issues, the problems they faced and successes they have enjoyed may provide important insights for countries planning to establish their own system. This does not mean that other countries have not attempted to protect TK and genetic resources in their jurisdictions. Several countries have enacted laws\(^{458}\) providing procedures for access to and benefit sharing from genetic resources and TK, and outlined the rights and duties involved.

The priority of the codification initiatives is to save the body of knowledge from loss and to stop acts of ‘biopiracy’ i.e. to invalidate non-innovative TK-based patents claimed by outsiders. None of the codification initiatives seem to be oriented towards making TK easily accessible to outsiders for use in producing TK-based products and services. Security measures have been taken to ensure that the codification is not accessed by unauthorized persons. A couple of the databases are documented in local languages and investment is not made to translate them into other more accessible languages. A key reason for this defensive orientation is the lack of recognition and legal protection of positive rights in TK. These restrictions are part of the protectionist trend described in the previous chapter. The limited positive use of TK is focused on helping local communities to the exclusion of outsiders. While codification to save TK from loss is commendable and is rightly the priority of these initiatives, the positive use of the TK codified in

\(^{457}\) For a list of TK databases and for discussion of the implications of TK databased for protection, see Inventory of existing online databases containing traditional knowledge documentation data, supra note 236.

\(^{458}\) The Secretariat of the Convention on Biodiversity has a database of countries that have adopted legislations on Access and Benefit Sharing (ABS) of genetic resources and traditional knowledge. According to the database seven regions and fifty seven countries have adopted some type of legislation on ABS. Secretariat of the Convention on Biological Diversity, supra note 166; For a comprehensive discussion of national and international experiences, see note 166; For a comprehensive discussion of national and international experiences, see Eduardo Velez, Brazil’s Practical Experience with Access and Benefit Sharing and the Protection of Traditional Knowledge, Policy Brief 8 (International Center for Trade and Sustainable Development, 2010).
these databases holds great potential for the production of products and services for the global public. It is the core thesis of this dissertation that a legal mechanism that recognizes positive rights in TK would encourage investment in these databases and facilitate the proactive use of TK.

5.1.1 India

The leading national project to codify TK is the Traditional Knowledge Digital Library (TKDL) of India. The project was the government’s way of responding to several biopiracy instances that saw the granting of patent rights related to Indian traditional knowledge including for ‘inventions’ related to turmeric and the neem tree. Some of these patents have been revoked after public outcry and as a result of the prior art (the codified TK) disclosed in post-grant opposition mechanisms.

The TKDL has recorded “1200 Ayurvedic, Unani, and Siddha Formations with various sub-groupings.” And the TKDL uses a novel “Traditional Knowledge Resource Classification” similar to that of the International Patent Classification and is translated from Sanskrit into six languages (English, French, Spanish, German, Japanese and Hindi) to make the database accessible. The translations may become essential in supporting the work of the major patent filing jurisdictions called the IP5. The TKDL is being used defensively. In the time between its first use in a patent proceeding in July 2009 and October 6, 2014 it was involved in at least 201 patent applications in some form; and it has resulted in the rejection of applications, the revocation

459 Traditional Knowledge Digital Library (TKDL) supra note 159.
461 For an up-to-date involvement of the database in patent prosecution, revocation or amendment, see the “About the TKDL” section, Traditional Knowledge Digital Library (TKDL) supra note 159.
462 Gupta, supra note 425 at 10.
of patents rights, and the amendment of claim(s) or withdrawals by applicants.\textsuperscript{464} This shows that TK databases that are made globally accessible can be an effective defensive tool against biopiracy. The TKDL has reported a 44\% decline in patent applications related to Indian medicinal knowledge to the European Patent Office.\textsuperscript{465} India has signed agreements with patent offices in other countries to implement the confidential use of the TKDL.\textsuperscript{466} The contents of the TKDL are made available to patent examiners under conditions of confidentiality and content is delivered through a secure digital system.\textsuperscript{467}

As argued earlier, even if the use of the TKDL may be successful in reducing biopiracy, the real potential of such a knowledge base is in making it accessible. If proper recognition and protection is given to this type of codified TK, knowledge holders will be encouraged to invest in setting up similar systems that may be easily accessed for personal use as well as for R & D projects worldwide. If a protection system that increases confidence among both the knowledge provider and user sides is established it can encourage collaborative and continued research. As stated earlier in this chapter, if tacit knowledge, which cannot be easily codified, becomes important in further research and development of TK, it would create a continued and collaborative relationship between TK holders and users. Innovation in TK could work hand in hand with innovation in modern medicine consistent with the WHO’s integrated medical systems.\textsuperscript{468} The best scenario is not one where secret knowledge is used to block non-inventive patents, but one where that knowledge is used in products and services that help patients in need of treatment. Thus, a positive protection that encourages codification, disclosure and commercialization of TK seems to be the best way forward.

\textsuperscript{464} Traditional Knowledge Digital Library (TKDL) \textit{supra} note 159, Major Milestones.
\textsuperscript{465} World Intellectual Property Organization, “Protecting India’s Traditional Knowledge”, \textit{WIPO Magazine} (June 2011), online: \texttt{<http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html>}.
\textsuperscript{466} Traditional Knowledge Digital Library (TKDL) \textit{supra} note 159.
\textsuperscript{467} Gupta, \textit{supra} note 425 at 10.
\textsuperscript{468} For a discussion of the World Health Organization’s Integrated Medical Systems, \textit{see} Section 1.8 under Chapter One.
The TKDL is not the only initiative of its kind in India. The Honey Bee Network established in the late 1980s, is a famous TK innovation pool which has since then established networks in 75 other countries.\textsuperscript{469} This network includes individuals and organizations in communities, academia, government and the private sector.\textsuperscript{470} It works as a ‘knowledge pool’ type of system in which members give back any innovation they develop based on the TK in the pool, thereby helping it grow.\textsuperscript{471} While the network claims to have over one million TK related “ideas, innovation and traditional knowledge practices”\textsuperscript{472}, other reports suggest that the database hosts more than 10,000 improved knowledge references.\textsuperscript{473} The core principles of the network are the attribution of sources of TK, the sharing of fair benefits and the creation of communication networks between communities.\textsuperscript{474} The network seems to be the oldest TK database discussed in this section and the only one which involves international collaboration in TK use. It has a relationship with the South African database referred to below. Although it is not clear whether the network has a positive application of TK, it can be inferred from the benefit sharing requirement that there is something similar to positive protection.

5.1.2 China

China has two Traditional Chinese Medicine (TCM) searchable databases. One is run by the Chinese State Drug Administration (SDA); the other is managed by the Institute of Information on Traditional Chinese Medicine.\textsuperscript{475} While the former hosts bibliographic data of 30 TCM databases all in Chinese, the latter has 18 TCM databases in Chinese and two in English.\textsuperscript{476} The

\footnotesize
\begin{itemize}
\item \textsuperscript{469}“The Honey Bee Network”, online: <The Honey Bee Network> See sections on "How did it all begin? and “About us.”.
\item \textsuperscript{470}The Honey Bee Network, About us sections, available at http://www.sristi.org/hbnew/genesis.php last accessed November 24, 2013
\item \textsuperscript{471} Kaushik, supra note 460 at 87.
\item \textsuperscript{472} The Honey Bee Network \textit{supra} note 468, See the “About us” section.
\item \textsuperscript{473} Kaushik, \textit{supra} note 460 at 87.
\item \textsuperscript{474} The Honey Bee Network \textit{supra} note 468, See sections on “How did it all begin?” and “About us.”
\item \textsuperscript{475} Traditional Chinese Medicine \textit{supra} note 340.
\item \textsuperscript{476} Sun, \textit{supra} note 332 at 23.
\end{itemize}
Chinese version has 31,283 formulations while the pilot project in English has over 12,000 and covers the years 1985-2002.\textsuperscript{477}

The rationale for creating the databases was “to meet the increasing need of patent examination.”\textsuperscript{478} There is no evidence, however, that the databases have been used by any entity other than the State Intellectual Property Office of China. The databases use 29 fields of classification in four categories in both the Chinese and English version of TCM.\textsuperscript{479} It seems that neither databases use a system similar to the International Patent Classification as was done in the India. The database also provides a dictionary in Chinese that can be used in searching for TCM practices and translating them into English, Latin or scientific terms.\textsuperscript{480} It seems that, compared to India, China is not so keen to document its knowledge in languages accessible to users and patent examiners in other countries. Similar to the TKDL, the Chinese databases are used defensively. Additionally, since the databases are mostly in Chinese languages, translating them and making them more accessible would require significant investment.

\subsection*{5.1.3 South Korea}

South Korea’s Traditional Knowledge Portal (KTKP) is a fully searchable database with both Korean and English content.\textsuperscript{481} It hosts articles related to TK from 47 journals (periodic publications) collected from eastern medicine, cytology, and pharmacy as well as life science journals published from 1947 – 2010 available to patent examiners through an online portal.\textsuperscript{482} There has been an impressive increase in the number of applications for oriental medicine based on plants and there has been a substantial increase in demand in the cosmetics market for products

\begin{thebibliography}{99}
\bibitem{477} “Brief Introduction of China Traditional Chinese Medicine (TCM) Patent Database”, online: \url{<http://221.122.40.157/tcm_patent/englishversion/help/help.html>}.\textsuperscript{478}
\bibitem{478} \textit{Ibid.}\textsuperscript{479}
\bibitem{479} \textit{Ibid.}\textsuperscript{480}
\bibitem{480} \textit{Ibid.}\textsuperscript{481}
\bibitem{481} “The Korean Traditional Knowledge Portal”, online: \url{<http://www.koreantk.com/en/m_about/about_01.jsp?about=1>} See section on “About KTKP”.\textsuperscript{482}
\bibitem{482} Choi, \textit{supra} note 333 at 9.
\end{thebibliography}
based on TK.\textsuperscript{483} The database stewards have adopted the International Patent Classification system and the contents include knowledge in medicine, agriculture, lifestyle and food.\textsuperscript{484}

There is no strong evidence of a positive use of the knowledge collected in KTKP. It seems the knowledge is being used defensively similar to India’s TKDL. However, there is at least one instance of a Korean firm developing a drug that treats arthritis by integrating Korean traditional knowledge in the healing abilities of tree plants and modern pharmacology methods.\textsuperscript{485} South Korea has not escaped the growing number of disputes over patents granted on TK. Nestle’s process patent over a “method of flavored vegetable” has been revoked because of its “similarity with Kimchi.” However the revocation was made only in South Korea.\textsuperscript{486}

5.1.4 South Africa

Recently, South Africa announced that it would launch a similar depository of indigenous knowledge in different parts of the country with the aim of documenting oral TK.\textsuperscript{487} The plan to initiate the National Recordal System (NRS) is based on the country’s Indigenous Knowledge (IK) policy which insists that codification is necessary if knowledge holders are to share benefits arising from the use of TK.\textsuperscript{488} The objective of the project is the “promotion, protection and preservation” of TK with complementary work being done to develop the knowledge and set up an Indigenous Knowledge patent system.\textsuperscript{489} The National Indigenous Knowledge Management System (NIKMAS) is the digital version of the depository through which TK will be collected,

\begin{footnotesize}
\begin{enumerate}
\item\textit{Ibid} at 3 & 6.
\item\textit{Ibid} at 10 & 12.
\item\textit{Ibid} at 4.
\item\textit{Ibid} at 8.
\item Council for Scientific and Industrial Research (CSIR), \textit{supra} note 334; Saez, \textit{supra} note 334.
\item Introduction to Indigenous Knowledge Systems Documentation Centers (IKSDC) (Emothonjeni Healing Center, University of Fort Hare).
\item Tom Suchanandan & Carol van Wyk, \textit{The National Recordal System: Presented to the National Biodiversity Initiative} (Republic of South Africa - Department of Science and Technology, 2013) at 8.
\end{enumerate}
\end{footnotesize}
preserved and securely disseminated from local collection centers. It adopts four levels of access with varying privileges: confidential access to scientists who will work to develop the IK; restricted access to patent examiners around the world for use in prior art search; public access in order to promote IK; and community access granted to indigenous communities with the goal of preserving the knowledge base.

The South African database is planned for use in both the positive and defensive senses, which seems an improvement on other national experiences. A benefit-sharing application form available online is expected to make the system more accessible. The umbrella NRS project is expected to adopt a “holistic” and “living lab approach” to collecting IK. The following recording standards are planned: International Classification of Diseases, International Patent Classification, and the Dublin Core Codes. Although the NRS is still being developed, significant work seems to have been done towards completing the project. The more contentious issues of determining the scope of rights and benefit sharing can be expected to be clarified as the process unfolds. It has been reported that convincing community members of the value of using the system was difficult because they were distrustful of outsiders, especially in the case of traditional healers for whom the limited availability of TMK is essential for their livelihoods. Other countries planning to develop a TK database should take note and ensure that prior consultations with knowledge holder communities have been done so as to establish a feeling of ownership of the system.

\[490\) Ibid at 4.

\[491\) Ibid at 10.

\[492\) Ibid at 3.

\[493\) Saez, supra note 334.

\[494\) Suchanandan & Wyk, supra note 489 at 5.

\[495\) Ibid.

\[496\) Saez, supra note 334.
5.1.5 Venezuela

Biozulua, which means ‘house of life,’ is a Venezuelan digitized TK database. It followed research conducted by The Foundation for the Development for the Physical and Mathematical Sciences (FUDECI) in Venezuela with the goal of saving TK which faces a risk of extinction. It focuses on TK dependent on genetic resources and includes therapeutic, agronomic and technological knowledge. It documented the genetic resource and TK associated with it that could be used in modern medicine. The codification is highly digitized, supported by multimedia and “referenced based on satellite position systems” to show the source community’s location. It succeeded in systematically codifying “3,000 biological specimen collections and 20,000 data items.”

The database was organized in a way that will allow parts of it to be modified to meet the changing needs of codification. As discussed earlier, the flexibility of databases is essential in accommodating the differences between cultures and the unique contextual nature of TK. The experience of the Biozulua will be useful in crafting such a system. A core objective of the Biozulua database is to share the codified TK with the knowledge holding community so that it can supplement or replace the traditional ways of knowledge transfer. This seems to be a feature in common with the proposed database in South Africa and the Honey Bee Network. The re-communication of TK to the source community is an important element that should be duplicated in other database projects. It allows knowledge holders to innovate to meet their own needs and creates the feeling of continued ownership.

497 Zent & Zent, supra note 335 at 105–6.
498 Ibid at 105.
499 note 237 at 16.
500 Ibid at 17.
501 Ibid.
502 Zent & Zent, supra note 335 at 106.
503 note 237 at 17.
504 Zent & Zent, supra note 335 at 105–6.
Although the initial stages of the Biozulua project's were positive, it faced a challenge when the owners of the database disclosed their intention to apply for a right to exclude the public, including the knowledge providers, from accessing the database.\textsuperscript{505} The decision was based on a “noble” intention to avoid risks associated with the absence of protection of TK and the potential of considerable economic gain that could result from commercialization.\textsuperscript{506} The announcement resulted in passionate objection from knowledge providers who called for the return of their knowledge and the withdrawal of all research and documentation related to the project.\textsuperscript{507} The reaction may be justified when seen in light of past experiences of other knowledge providers. This example shows the tension that might arise in cases where the value of the knowledge base is recognized but there is a lack of recognition, or there is ambiguity relating to its legal protection. A clear procedure for prior informed consent and a general framework for benefit sharing should be adopted at the beginning of such projects. A legislative framework that can govern such relationships between TK holders and users will help ease tensions in similar scenarios.

These national attempts at recognizing, documenting and disseminating TK are encouraging and should be replicated by other national governments so as to codify TK that would otherwise be lost. Not only are the databases valuable in that they prevent TK from being lost, but they also facilitate its dissemination through the establishment of a ‘common code.’ Efforts at the regional and international level are slow, and developments in national jurisdictions could have the effect of speeding up initiatives for the protection of TK at the international level. Any such initiative should take into consideration the above-stated expectations of both knowledge users and providers. These include a fair and balanced system of codification which establishes clarity and is easily accessible. TK databases do not have to be limited to defensive protection as there is real potential for TK to improve social welfare in other communities and countries. Plans to start TK databases should adopt the lessons\textsuperscript{508} that countries such as India, China, South Korea, South Africa and Venezuela have learned through experience.

\textsuperscript{505} Ibid at 106.
\textsuperscript{506} Ibid.
\textsuperscript{507} Ibid at 105.
\textsuperscript{508} For a discussion of the lessons learned from the experience of states, see note 68, Section III, B.
5.2 International Database Initiatives

There is no international database that collects and protects TK in the context discussed in the previous section. Although the Honey Bee Network has collaborators in more than 75 countries, it seems to be a more loose collaboration rather than a comprehensive attempt to codify, protect and disseminate TK globally. There are, however, international treaties that discuss or support the establishment and protection of TK in national jurisdictions. A brief discussion of such initiatives is provided below.

The WIPO has embraced national attempts at establishing a TK database and has adopted a policy of supporting governments in that endeavor. It has established a fund to be used to train members of indigenous and local communities to document their own knowledge and culture. The system takes a bottom-up approach and has been praised as innovative for its empowerment of indigenous and local communities. There is evidence from at least one project that WIPO is involved in - the documentation of the Maasai community’s cultural expressions and traditional knowledge. Additionally, the WIPO has prepared a draft toolkit that can be used by national governments in establishing a TK database. Although still in a draft form, the toolkit provides a list of recommendation on how to best establish a TK database including advice on planning, obtaining consent from indigenous community members, securing content before, during, and after documentation. The WIPO also serves as a registry of national TK databases which currently lists the national attempts in India, China, and South Korea discussed above.

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509 Genesys is a world-wide portal that documents information submitted by gene banks from different corners of the world and makes it accessible to users. While this system is global in nature its focus is on genetic resources for food and agriculture, and therefore it will not be discussed in further detail. For more on the work of Genesis, see “Genesys: Gateway to Genetic Resources”, online: <https://www.genesys-pgr.org/welcome>.


511 A video of the project is available at the WIPO Traditional Knowledge webpage. See Andi Gitow, Digitizing Traditional Culture in Kenya (Kenya: UNTV and WIPO).

512 WIPO, supra note 435.

513 Ibid.
The United Nations Convention to Combat Desertification (UNCCD) calls for the provision of exclusive rights over new content in TK databases.\footnote{The convention is arguably the only international treaty that expressly calls for the proprietary protection of TK. Carvalho, supra note 3 at 263.} The UNCCD is one of three conventions arising out of the Rio Earth Summit in 1992.\footnote{“United Nations Convention to Combat Desertification (UNCCD), About the Convention”, online: <http://www.unccd.int/en/about-the-convention/Pages/About-the-Convention.aspx>.} It addresses the protection of TK databases through the narrow lens of its focus areas: desertification and land degradation.\footnote{Carvalho, supra note 3 at 264.} The relevant articles of the convention: Article 16 (g), 17 (1, c) and 18 (2) all refer to TK databases, their protection and benefit sharing. While Article 16 generally sets the stage for protection of TK, Articles 17 and 18 provide further detail.

Nuno Pires de Carvalho argues that, because of the use of the term ‘ownership’ rather than ‘right of remuneration’ under article 17 (1, c), the UNCCD is expressly calling for IP protection of “original” contents of TK databases.\footnote{Ibid at 263.} The convention does not specifically call for IP protection of TK databases and the inference of IP protection from general terms like ‘ownership’ might be a weak one. The analysis that Carvalho provided is reasonable, however, to the extent that the proposed regime is a proprietary one. Under Article 18 (b) signatories have agreed to “ensure … that local populations benefit directly … as mutually agreed, from any commercial utilization of [TK] or from any technological development derived therefrom.”\footnote{United Nations Convention to Combat Desertification, UNCCD, 1992 [United Nations Convention to Combat Desertification] at Article 18 (2,b).} The convention calls for the adoption of a property rule system rather than a liability rule system when it states that benefit sharing should be based on \textit{mutual consent}. This wording shows that knowledge holders could refuse to give consent, which is a privilege that comes with proprietary regimes. This should not, however, be taken to mean that the UNCCD is calling specifically for the protection of TK through existing IP laws, as Carvalho seems to claim, but that any form of protection adopted should be proprietary. Thus, a sui generis system that recognizes proprietary rights over original contents of TK database could satisfy the UNCCD obligations, despite not be an IP regime per se.
It should be noted that the UNCCD’s objective in calling for the protection of TK is based on both static and dynamic efficiency: the goal is conserving existing TK from loss and “promoting the creation of new TK.” Even though the provisions of the convention seem strong, the duties of member states under the convention are subject to “respective capabilities … and national laws and/or policies.” Thus, the effectiveness of enforcement measures under the convention are highly limited and will be difficult. While the UNCCD Secretariat runs a library that collects relevant resources, including “gray documents” (resources from local communities), it does not itself host a TK database. It gives the responsibility of setting up databases to member countries.

Lastly, some vague connections have been made between the Trade Related Intellectual Property Rights (TRIPs) Agreement and TK. The TRIPs treaty does not mention the protection of TK. However, it has been remarked that TRIPs Article 39.3’s requirement that member states take measures against unfair commercial uses of clinical trial data sets could be used to justify the creation of a system of protection for original TK codified in databases. The analogy drawn seems to be as follows. The protection against unfair commercial uses of clinical trial dataset, commonly known as ‘market exclusivity’ or ‘data exclusivity’, gives a brand company that produces new drugs, protection against unfair competition from generic companies for a limited period of time. Such protection is conditional on the competition (usually a generic company) using the clinical trial data set of the brand company to gain marketing approval. The rationale for protection is to allow brand companies to recoup the considerable expenses they incur in the various clinical trials they make on different drugs from the exclusive marketing of their

519 Carvalho, supra note 3 at 264.
520 United Nations Convention to Combat Desertification, supra note 518 at Articles, 16 (g), 17 (c) and 18 (2, a & b).
522 World Intellectual Property Organization, supra note 429 at para 50.
524 Ibid at 482.
successful drugs.\textsuperscript{525} Since a clinical trial data set, a codified knowledge of the trials and errors of the brand company, resembles TK which is a collection of trials and errors of indigenous and local communities accumulated over centuries, TK should justifiably get a similar treatment.

The argument seems reasonable in that it seeks to cite the closest available IP protection to justify the creation of a protection system for TK. However, the provision cited does not explicitly provide protection for clinical data sets but asks that member countries take measures against unfair commercial uses, thereby reducing the effectiveness of the analogy. Instead of extending existing IP laws in an attempting to fit TK protection, the argument would be stronger if existing IP laws are used to make analogies to craft a system suitable for TK databases. For example, the protection of market exclusivity is for a limited period, while knowledge providers might want to get protection for contents in a TK database for a longer period of time or for as long as it is kept secret. A system of protection should be reflective of the special features of TK if it is to be effective. In any case, while the argument provided may be convincing, it has not been developed further. As a result, such a proposal is not seen in other international negotiations or documents relating to the protection of TK.

The above discussed national and international experiences with codification of TK are mostly recent (with the exception of the Honey Bee Network). They therefore provide a limited number of lessons. However, analysis of these early experiences is important for guiding future national and international initiatives. Governments and international entities working to set up a TK database for the purpose of both defensive and positive protection should learn from the experience of existing initiatives. The lessons so far may be generalized in the following way: the effective inclusion of knowledge providers requires constant consultation and training; informed consent of knowledge holders is necessary to manage a database successfully; once a database is established, instead of limiting its use to defensive methods, adopting a positive and developmental perspective holds huge potential; technological advancements could be used to make TK databases more accommodating of differences in TK and TK holding communities.

6 Conclusion

This chapter outlines the ‘incentive to codify’ argument based on the categorizations of TK as a public good in Chapter Two. Communities cannot reasonably be expected to invest in codifying their knowledge and disclosing it to outsiders without some type of protection and incentive. It posits that a carefully crafted legal mechanism will encourage TK holder communities to invest in the codification and disclosure of TK, thereby saving the body of knowledge from the alarming rate of loss it is faced with. The chapter is also a call to stakeholders for a shift in paradigm from focusing on cultural conservation as the key objective to knowledge codification. It argues that the incentive that knowledge holder communities need is to codify their predominantly orally-transmitted knowledge and not to conserve their culture in its authentic form.

Analogy is made to the way patent law encourages inventors to codify knowledge they would otherwise leave uncodified in order to make the case that legal intervention on TK would also create a similar incentive for TK holders to codify their TK. The literature on tacit and codified knowledge is discussed through this perspective. When knowledge moves from tacit to codified, it becomes easier to disseminate and commercialize. The same is expected to happen in the case of TK. Four key benefits of TK codification are identified. These benefits are: the potential of codification to establish a common code for the communication of TK to different communities; the preservation of TK from the alarming rate of loss it faces; the potential of legal protection in creating certainty with regard to the rights and responsibilities of stakeholders; and the notice and evidentiary function of TK codification.

While TK codification does have numerous benefits, it also has some limitations. One key limitation of a markets-based incentive may be that TK that does not have a readily commercial value may not be codified. However, market provision of TK is expected to be complemented by public sources of support such as government investment in the codification of TK that may not have a readily available commercial value. The chapter also examines other potential limitations that TK codification may have including the prohibitive costs of documenting all of the TK that a community might hold, the risk of unauthorized public access to codified TK, and the disruption that codification may cause to cultures that have been isolated from mainstream communities.
These limitations, however, call for a robust legal mechanism for TK codification rather than being reasons to reject codification altogether. Codification attempts should make full use of technological advancements to ensure the establishment of a system that reflects the needs of TK holders and users.

The chapter then examined the main interests that TK holders and users may have regarding TK codification. Although both groups are diverse, core features have been discussed with the hope that it may guide TK codification attempts. The chapter concludes with an examination of a few of the national and international TK codification initiatives currently taking place. It is advisable that other TK holding communities and megadiverse countries invest in codifying TK to save it from loss. Most of the existing TK codification projects have rightly prioritized the preservation of TK rather than investing in making TK more accessible for use by outsiders. Although the proactive and positive uses of TK in the production of products and services is a welfare improving scenario, TK holders cannot reasonably be expected to invest in such projects without a promise of some benefits from such investment. The legal intervention advocated in this dissertation could establish the confidence that TK holders require to invest in making TK more accessible.
CHAPTER FOUR: A MODEL LEGAL FRAMEWORK FOR TK PROTECTION

1 Introduction

This chapter addresses the questions of what form of legal protection is suitable in order to encourage the codification and disclosure of TK. It outlines a legal framework for the protection of codified TMK which builds on the public good and incentive to codify discussions in chapters two and three respectively. The framework proposes the establishment of a bioprospecting right over codified TMK to encourage investment in the codification and disclosure of TMK. TK holder communities (or their licensees) who codify and disclose TMK will obtain a bioprospecting right over such knowledge. This right will include an exclusive privilege to conduct research in bioprospecting projects that use codified TMK.

The requirements for obtaining such rights are discussed, and the scope of these rights is examined in terms of its breadth and term. The hypothetical case of the Goodya plant is provided in order to help explain the application of the proposed mechanism. This chapter then examines the nature and scope of codification that will be subject to the proposed bioprospecting right. The chapter concludes by examining the implications of TK codification and disclosure on subsequent patent applications by TK holders or their licensees. It also examines ways in which the bioprospecting right could build the interest of diverse stakeholders.

2 The Proposed Framework: A sui generis right

In a consultative workshop on TK, Graham Dutfield, a leading scholar in international IP law, suggested that because of the diversity of interests involved in TK protection what is needed is a ‘buffet of rights’ rather than one uniform regime. The bioprospecting rights described in the

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526 Graham Dutfield (Professor of International Governance, University of Leeds), Presentation at a workshop organized by the Center for International Governance Innovation, International Law Research Program, on
following section then is just one option in a ‘buffet of rights’ that could be used to address the complex issue of TMK protection. It should also be noted that the proposed mechanism is a voluntary system with respect to knowledge holder communities. It is plausible that some communities might not want to participate in the system for various reasons. Other mechanisms, such as keeping TK secret and contracting with users regarding access, could be implemented to address the concerns of communities who prefer to opt out of the proposed regime.

2.1 Definition and Purpose of the Bioprospecting Right

The ‘bioprospecting right’ proposed in this chapter is a cluster of rights that emanates from bioprospecting activity based on TMK. Depending on the type of TMK database, it includes an exclusive right to conduct bioprospecting, or a right to share profits of bioprospecting over TMK codified in a publicly accessible database, or a right to receive compensation for unauthorized bioprospecting on TMK codified in a restricted database. The right will be granted to source communities that codify their TMK either in a publicly accessible database or in a restricted database to which a government agency or other entity would have access. The two types of databases and rights emanating from them are discussed in detail in section 2.4.1 of this chapter.

The purpose of granting the bioprospecting right is to encourage the codification and disclosure of TMK. This ‘incentive to codify’ rationale has two sides to it: the supply and demand side. On the supply side, the regime encourages knowledge holder communities to codify and disclose their knowledge. On the demand side, it encourages entrepreneurs who want to help knowledge holder communities in codifying and disclosing their knowledge to invest in that process. Economic efficiency would require the granting of rights so long as it is efficient and necessary to meet these purposes.

1Emerging International Law Issues Related to Biodiversity, Traditional Knowledge & Cultural Expression: From Community Knowledge to a Knowledge Community, May, 2015 in Toronto, Canada.

527 See for instance, Long, supra note 310; Varadarajan, supra note 325.
2.2 Core requirements

There is a need to set parameters within which source communities that codify TMK will receive legal protection. This is necessary to ensure that the system works to encourage codification and disclosure without discouraging follow-on innovation. In this regard, the following four requirements should be put in place under the bioprospecting right.

First, the applicant must either be the knowledge holding community, a representative of the community or a person who has received Prior Informed Consent (PIC) from the knowledge originating community. If the applicant is a member of the knowledge holder community customary laws of that community should govern internal issues of ownership and application. But, if the applicant is an outsider, there is a need to ensure that the applicant has obtained consent from the knowledge holding community. Such a requirement is necessary to reverse the protectionist trend, a trend in which TK holders are increasingly becoming restrictive in terms of providing access to their TK and genetic resources. 528 Allowing anyone to receive rights over TMK without receiving consent from knowledge originating communities will further encourage a protectionist trend. These are the very scenarios the proposed regime seeks to avoid.

It is advisable to establish guidelines for how consent is received from a knowledge holding community to facilitate relationships between knowledge holder communities and outsiders interested in applying for TMK codification. These guidelines could outline recommended procedures and minimum standards with the goal of safeguarding the system from abuse and providing clarity and security to the parties involved. The Nagoya Protocol, which was signed to explain the Convention on Biodiversity further, calls on member countries to establish standards on the “prior informed consent or approval and involvement of indigenous and local communities” (PIC) in access to genetic resources and associated TK. 529 Since the goal in the bioprospecting right proposed in this chapter is to empower TK holder communities and to create

528 The protectionist trend is discussed in further detail in section 2.3 of Chapter Two.
529 The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity, supra note 131 at Articles 5, 6, 7.
the confidence needed to codify TK, the effective consent of TK holder communities is essential. Therefore, the jurisdiction in question should develop a suitable framework through which outsiders could receive the effective consent of TK holders.

Second, the applicant, if not a representative of the knowledge holding community, must have entered into a benefit-sharing agreement with the knowledge holding community. As with PIC, a guideline that outlines certain minimum standards might help facilitate the relationship and protect knowledge holder communities against abuse by sophisticated knowledge users. The Nagoya Protocol and its annex on ‘monetary and non-monetary benefits’ call for the ‘fair and equitable’ sharing of benefits under ‘mutually agreed terms.’ This framework could be used as a base to build an equitable benefit sharing guideline. Each jurisdiction should ensure that TK holders receive a ‘fair and equitable’ share of the benefits in agreements they enter into with licensees. Setting minimum standards and conditions may help in this regard, and it is necessary to avoid a repetition of the negative past experience where indigenous and local communities enter into agreements without understanding the nuances and implications of the agreement.

Third, the application must clearly specify the scope of the knowledge being claimed. It goes without saying that the knowledge that is expected to receive legal protection will have to be clearly stated. This is necessary for the purposes of codification, disclosure, and enforcement of rights. Without a clearly stated scope users will not know if they are infringing upon a right or what rights they are infringing upon. Intangible properties are inherently difficult to delimit compared to physical property which has physical limits. Therefore, clearly specifying the scope of TMK over which legal protection is sought is even more essential than is the case with physical property.

The level of disclosure and enablement required in patent laws should not, however, be required in the case of TMK. Prospecting by definition involves unknown elements of the available body of knowledge. The scope and potential of inventions covered under patent law may be estimated relatively easily compared to TMK used in bioprospecting, which will usually be general knowledge about the therapeutic features of a resource. As a result, the requirement of specifying the scope of the TMK claimed should include flexibility to respond to the unique features of TMK.
Moreover, traditional healers and members of the knowledge holding community may be unable to specify TMK in the way a scientist would be able to describe an invention. A system of protection which adopts a patent-like specification requirement risks being unworkable. Carvalho suggests setting up an easy requirement for the disclosure of “minimally enabling” information – information that would enable another person to comprehend what the Shaman does and to replicate it. A requirement of enabling disclosure along the lines of such standards might suffice for the proposed system.

Fourth, the knowledge claimed must not already be widely diffused. The more that knowledge is diffused the harder it is to find the community from which it originated for the purpose of assigning rights. The cost of locating the originating community and the uncertainty surrounding the question of which community to consult will discourage follow-on innovators from investing in building on the knowledge. However, this requirement begs the question of how diffused TMK has to be before it is no longer able to receive protection. This is a hard question to address and it may be impossible to set a clearly defined line. Instead, it may help to specify certain standards such as the ability of the applicant to produce evidence demonstrating the origins of the knowledge. Practicality would require the granting of protection to cases in which claimants produce satisfactory evidence supporting the community as the source of that TMK. Ultimately, courts would have to draw the contours of protectable TMK and that which is too diffused to belong to the applicant (claimant).

Along the lines of diffused knowledge, it should be noted that some TMK could be held by more than one community. This could be a result of historical connections between the communities or independent discovery. Multiple origins for the same or similar TMK might create challenges for the proposed system of TMK protection. It may also increase the costs of users in deciding with which community to consult. However, it is possible to respond to such situations through innovative flexibilities. For example, a ‘joint ownership’ type of right could be granted to multiple

530 Carvalho, supra note 13 at 261.
531 Ibid at 261.
communities that can prove to have created and developed the TMK. TMK databases would also be able to facilitate the establishment of joint rights.

2.3 Applying the Bioprospecting Right: The Goodya Plant

Since the previous sections provided the core requirements of the proposed bioprospecting right, a hypothetical case may be a useful tool to help explain these features. The case is provided to show what the scope of the right may be and what a narrow and broad scope of TMK codification could look like.

***

The Fan people - a community in a remote corner of the world uses the Goodya plant to treat depression. Before the traditional treatment, the patient has to first undergo a three-week training in which she has to learn all the spiritual songs of the Fan people and a dance called Hammer. The ritual for the treatment is only conducted on top of Mount Dashen - the highest mountain in the Fan people’s traditional territory – and is held after sunset because the spirit of ancestors is the strongest at such time. The Goodya plant grows on top of the mountain during the spring season. All adult members of the Fan people are required to attend the ceremony. The patient will sit in the center of the group while the Conga – the traditional healer – stands next to the patient, fully adorned in face-paintings and a ‘garment of the wise men.’ Other members of the community sit in circles around the patient. The patient’s family forms the first circle and close friends will form the second circle. Each circle represents the person’s closeness with the patient.

The ceremony takes two hours. The first part of the ritual takes approximately an hour in which the patient leads the group in a chant progressively increasing with intensity. When the traditional healer believes the patient is ready the second part of the ritual begins. This is when the healer, with the help of his first born son, makes the patient drink a beverage made of the Goodya plant. The juice is made with a mixture of spices and an extract of the fruits and leaves of the Goodya plant.
The healer picks the Goodya leaves and fruits when they are still green, he dries them in the sun, and grinds them into a powder. The powder is boiled for approximately half an hour before it is left to simmer an hour longer. The healer then pours the mixture into a clay pot which is custom made for this mixture. The mixture is kept for three weeks in underground storage before it is reheated for use a few hours before the ceremony. After the patient drinks the reheated mixture, she joins the rest of the community in the Hammer dance in which the spirits of ancestors are expected to join. At the conclusion of the ceremony, the patient is expected to drink the Goodya mixture daily for a full week. The healer checks in with the patient every night to see the progress she has made. Friends and family are also expected to visit the patient during this healing week.

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If the Fan people were interested in receiving protection under the proposed bioprospecting right they would codify and disclose their knowledge through an agency established for this purpose. The Conga – the traditional healer of the Fan people – or the chief may be authorized to act as a community representative under the customary law of the Fan people. Thus, either the Conga or the chief would be the contact person in the process of TMK codification and disclosure. The Fan people could also choose to enter into an agreement with a firm that could undertake the codification and disclosure of TMK. This agreement would have to fulfil the first core requirement of the bioprospecting right by meeting the requirements of Prior Informed Consent as set out in the Nagoya Protocol.

Determining what types of uses infringe upon the registered exclusive bioprospecting right and which uses are legal will be challenging. Here, it may be helpful adopt the ‘substantial reliance’ test suggested by William Fisher. According to the test, source communities would have rights against users who relied substantially on TMK in the production of inventions, products and processes. It is acknowledged that the ‘substantial reliance’ standard is a vague one that does not

532 William Fisher, “Two Thoughts About Traditional Knowledge” (2007) 70 Law Contemp Probl, online: <http://hdl.handle.net/10535/3232> at 133.
give sufficient direction regarding what types of uses will amount to infringement.\textsuperscript{533} However, the vagueness is necessary to allow the proposed mechanism to cover the diverse ways in which outsiders use TMK. The court or other entity adjudicating the claim of infringement of a bioprospecting right would examine all the evidence and decide if the user relied on TMK to such a degree that it is a ‘substantial use’. The simple act of a user obtaining access to codified TMK should not be considered substantial reliance on such knowledge. But situations in which the use of TK enabled users to save time and/or resources in the production of the final product should usually be considered to meet the ‘substantial reliance’ test. Additionally, substantial reliance should also be found in cases in which the use of TK changed the research direction significantly in a way that enabled users to produce a successful product.

Since courts currently engage in similar exercises in enforcing patent laws, they could develop jurisprudence regarding the appropriate parameters of ‘substantial reliance’. The doctrine of equivalents allows courts to decide that an act ‘substantially similar’ to the patented invention infringes if it does ‘substantially the same function, in substantially the same way, to yield substantially the same result’.\textsuperscript{534} Acts that are substantially similar to those stated in the patent claim would be considered infringements. The substantial reliance standard could also be developed by courts in the same way that they developed the doctrine of equivalents. In the hypothetical case provided above, the Fan people will have the rights outlined below (see Section 2.4.1) against users who relied substantially on the codification of TMK related to the Goodya plant.

The third core requirement of the bioprospecting right may help in the above-discussed analysis. The documentation of TMK has to state clearly what the knowledge is in as much detail as possible. In the case of the Goodya plant, the documentation should provide the TMK with as much context as possible. This includes the traditional and scientific name of the plant, how the

\textsuperscript{533} Ibid.

plant is used, and the expected effects of the plant. Further discussion on the nature and scope that TMK codification should take is provided in Section 2.4 below.

The final core requirement is that the knowledge should not already be widely diffused. Any part of the codified knowledge of the Goodya plant, the procedures followed in providing treatment, and its ability to treat depression, would not be under the exclusive right of the Fan people if already widely diffused. A challenging task here is in determining how diffused TMK has to be before losing its ability to be protected under the proposed system. This challenge becomes even more essential given the prevalence of multiple communities holding variations of similar TMK. The fact that another community uses the Goodya plant and its procedures to treat depression should not exclude it from protection. If these communities are found in close proximity to one another yet secluded from mainstream communities, there is still value in protecting this knowledge in order to encourage its codification and disclosure. The two source community could be considered co-owners. However, the more mainstream the communities are, and the more communities there are that hold the knowledge, the narrower the scope of the bioprospecting right. In other words, based on the ‘substantial reliance’ standard, the more diffused a TMK is, the less that users rely on TMK from one community. If users did not rely substantially on a codified TMK, then bioprospecting rights cannot be claimed.

For instance, if communities neighboring the Fan use a different species of plant that has the same family as the Goodya plant, the Fan people’s bioprospecting right could be limited to the use of the Goodya plant and the other community could have rights over other types of plants they use to treat depression. If a community documents one variety or species of the plant, and the user firm conducts research on another variety with more promising potential, the source community’s right depends on how much the firm relied on the first variety/species to understand the value of the second plant variety/species. This is because a community could only claim part of TMK codification that the community holds to the exclusion of the outside world. Similar to the issue of infringement, this issue would also have to be addressed through courts or legislation. However, attempts should be made to establish co-ownership when communities hold the same or similar TMK in order to facilitate its use by outsiders and the benefit sharing process.
Now that the hypothetical example of the Goodya plant has been used to explain how the core requirements of the bioprospecting right would be applied, it is appropriate to discuss the scope of such right.

2.4 Scope of the Bioprospecting Rights

The economics literature suggests that exclusive rights on knowledge goods increase the cost of follow-on innovation and can deter it all together. Therefore, the granting of exclusive rights over such goods should be justified through innovation-enhancing effects of such rights. The welfare gains from an increase in the rate of invention – caused by the incentive of gaining a right - should be greater than the deterrence of follow-on innovation.\textsuperscript{535} It is not an easy task to investigate the right scope of protection that would encourage optimal codification and disclosure; however, an attempt should be made to carve out a justifiable scope and balance the interests of knowledge holders, users, and the general public. The optimal scope, in terms of economic efficiency, of such a right is that which encourages the maximum codification and disclosure of TMK by knowledge holders without overburdening follow-on innovation.\textsuperscript{536}

It is challenging to determine what the optimal scope of a bioprospecting right should be to achieve the goal of encouraging optimal TMK codification and disclosure. To date, there is no agreement on the optimal scope of intellectual property rights.\textsuperscript{537} Any attempt to establish an optimal scope for TMK is only made harder because the market has not yet fully responded to TMK.\textsuperscript{538} The exact scope of the right will be highly affected by the policy objective of the country adopting the regime. Although there are bound to be differences in scope from one country to another, there are nonetheless core factors that should be considered in setting the scope of bioprospecting rights. Policy makers setting up the proposed regime will have to consider which

\begin{itemize}
\item \textsuperscript{535} Posner, supra note 289.
\item \textsuperscript{536} Ebermann, supra note 110 at 163.
\item \textsuperscript{537} Posner, supra note 288 at 58-59.
\item \textsuperscript{538} Carvalho, supra note 13 at 268.
\end{itemize}
factors to give priority to based on the jurisdiction’s interests. Below is a discussion of some of the factors that could affect the scope of the proposed bioprospecting right.

The scope of a bioprospecting right could be described in terms of its breadth and length. The breadth of the right relates to what the right holder will be able to rightfully claim. Breadth outlines the scope of the bioprospecting right within which rights and obligations arise. The length of the right refers to whether the right expires, and at what time and under what conditions. Different scopes of the bioprospecting right can be expected to have different effects in encouraging applicants to codify and disclose TMK. It can be expected that the larger the scope, the more that applicants would be encouraged to invest in TMK codification. However, the scope should also not overly reward applicants with a right which is too broad.

2.4.1 Breadth of the Bioprospecting Right

The breadth of the bioprospecting right relates to the limits of the right within which the right holder has legally protected interests. In contrast to rights over physical property, the limits of rights over intangible property are harder to delimit. Despite this challenge, the law has been able to set out legal ‘fences’ that set out the breadth of rights over intangible property. Here, it may be beneficial to draw an analogy to similar types of protection in patent law. A patentee receives the exclusive right to make, to use, and to sell the patented invention. The breadth of a patent right depends on the specific claims that are approved by the patent office. Users who make, use or sell inventions covered under a claim would thus be infringing upon the patent right. A similar claims-based right, but one that reflects the unique features of TMK and the bioprospecting process, could be set up for the proposed right.

If the proposed system is to attain its full potential, a core difference that cannot be avoided is the differing levels of interest in making the documented TMK either publicly accessible or restricted. Thus, the below section analyzes two types of TMK databases and rights that arise from them.

Two Types of Databases:
The scope of a bioprospecting right would depend on the type of disclosure (type of TMK database). There would be two types of databases: a publicly accessible database and a restricted database. TMK in a restricted database will only be accessible to the source community and the relevant agency with which the TMK is registered. The reason for creating two types of databases relates to the need to encompass communities with differing interests.

The ideal scenario in terms of innovation may be the disclosure of TMK in a publicly accessible database. The public accessibility of the database will inform users in industry about the existence of the knowledge. Publicly accessible databases will also create spillover effects that spur innovation. For instance, the accessibility of the TK database could reveal an important piece of information to researchers in a seemingly unrelated field.

However, some knowledge holder communities and their licensees might be opposed to the public disclosure of their TMK. Communities may seek to keep their TMK secret because it is against their world view to make the knowledge publicly accessible and to commercialize it. Other communities might be opposed to public disclosure because they want to commercialize their TMK while keeping it a secret. In both cases, there is an efficiency argument for encouraging these actors to invest in the documentation of a disappearing body of knowledge. If the proposed protection was made conditional on the actors publicly disclosing their TMK, it might result in excluding these two groups. A system which encourages the documentation of TMK in a restricted database should be preferred over one that simply allows bodies of knowledge to disappear.

The discussion of restricted TMK database hints at the possibility of protecting the knowledge through laws that govern trade secrets. Scholars have proposed the protection of TMK through trade secret laws. Trade secret law does not have many rigid requirements. Information which is not publicly accessible and provides its holder with a competitive advantage in its business could be protected under this regime so long as the owner takes reasonable measures to keep the

539 See generally Long, supra note 310; Varadarajan, supra note 325.
knowledge from falling into the hands of unauthorized persons.\textsuperscript{540} The absence of sophisticated requirements for protection makes trade secret regimes the apparent candidate for TMK protection. However, the core problem identified in this dissertation – the alarming rate of TMK loss – would not be sufficiently addressed through such regimes. Trade secret regimes are not designed to encourage the documentation of secret knowledge.

In order to respond to the unique features of TMK, trade secret regimes could be modified to encourage TMK documentation. This is where the protection of restricted TMK databases becomes important. The protection of bioprospecting rights in restricted TMK databases is similar to trade secret protection in that it does not require the public disclosure of information. However, the active encouragement of TMK documentation would be an inherent part of such a system.

The protection of restricted TMK databases would encourage two groups of communities that are interested in using such regimes. It would allow communities interested in commercializing their TMK while preferring to keep it secret to codify their TK in restricted databases. The framework provides them with the necessary legal rights on which to base their negotiation. It will also encourage communities not interested in commercializing TMK at all to invest in documenting their TMK to prevent it from loss. These types of database could be used as a repository of TMK and as evidence of the existence and ownership of the TMK.

In order to facilitate the licensing of TMK in both public and restricted databases, the database could include information on the ways in which users could obtain a license from the knowledge holding community or their representative. The information could include the name and contact address, any rules and practices that may have to be followed to receive a license etc. In restricted databases, TMK would not be fully disclosed, but a general statement could be included to guide potential users in their licensing initiatives. This feature of TMK databases could save significant transaction costs for the bioprospecting industry.

\textsuperscript{540} For example, see \textit{Uniform Trade Secrets Act}, National Conference of Commissioners on Uniform State Law, August 1985, UTSA \textit{[Uniform Trade Secrets Act]}, s 1.4.
Two Types of Rights:

The two types of TMK databases discussed above should give rise to two sets of rights that are consistent with the features of the database.

Rights in Publicly Accessible TMK Databases:

There are two alternative frameworks of granting the right over TMK disclosed in a publicly available database. The first is to grant source communities an exclusive right to undertake bioprospecting based on the publicly disclosed TMK. The right would include the exclusive right to make, to use and to sell products and services that result from the bioprospecting project based on the documented TMK. Since most knowledge holder communities may not have the resources required to commercialize their knowledge it can be anticipated that they will license these rights in whole or in part. Interested users could license this right from the right holders and the particularities of the license would be left to the parties to decide. Because of the unpredictable nature of bioprospecting, this framework could be expected to establish a royalty-based system in which users would share profits with right holders only if they have been successful in producing a product based on the particular TMK. An upfront lump sum payment combined with royalty payment is also common.

If such framework is adopted there is a risk that the source community would have an incentive to over-claim the value of TMK by listing a long list of conditions that the TMK covers without necessarily having used the TMK for such conditions. Since right holders would have the power to grant or refuse consent for bioprospecting over the TMK, they can use this powerful right and over-claim the value of TMK. If parties to a license establish a royalty-based system in which fees are paid only if there is a successful product, the incentive to over-claim will be reduced. However, right holders could insist on up-front lump sum payments instead of a royalty-based fee system, and therefore still have an incentive to over-claim.

In patent laws of several jurisdictions there are doctrines designed to reduce the incentive to over-claim. A key doctrine in this regard is the requirement that inventions have ‘utility’. Patent
applicants are required to establish the utility or usefulness of an invention either through demonstration or through ‘sound prediction.’ To benefit from the doctrine of ‘sound prediction’ patent applicants have to show, through a combination factual statements and sound line of reasoning, that the claimed invention could be expected to do what the patent claims. Additionally, patent specifications are required to disclose enough information to allow a Person Having Ordinary Skill in the Art (PHOSITA) who follows the instructions to produce the claimed invention. While these requirements may reduce the incentive to over-claim in patent applications, it is challenging to adopt similar requirements for the bioprospecting regime proposed in this chapter. This is because source communities may not be able to explain their TMK in scientific terms to meet the standards of sound prediction. Additionally, requiring that TMK codification include explanations on how it addresses certain conditions can be expected to increase the cost of codification, which in turn may reduce the incentive to codify TMK.

The second alternative framework is to grant source communities a right to benefit from successful bioprospecting projects based on TMK disclosed in a publicly accessible database. In this framework, users would be allowed to start bioprospecting without having to obtain consent from the source community. If and when a successful product is produced using the publicly disclosed TMK, right holders would have the right to an appropriate share of the profits. The exact share of the profits could be calculated by a court, a tribunal or an agency based on an estimated contribution that the TMK made to the final product. Reichman has proposed a similar ‘liability rules’ framework in which users are allowed to use available knowledge and are only required to share benefits once a successful product is produced.\(^\text{541}\)

There is a risk of over-claiming within such a framework as well. However, because of the reduced power of the right, source communities will have a highly limited incentive to over-claim. Source communities can claim their right to a share of the profits only if there is a successful product produced through a ‘substantial reliance’ of the publicly disclosed TMK. Because there is hardly any chance that TMK that has never been used to treat a condition could prove to be useful in treating that same condition, there is little incentive to over-claim. Even if source communities

\(^{541}\) Reichman, *supra* note 233; Reichman & Lewis, *supra* note 5.
over-claim, they have to overcome the challenging burden of proving that users relied substantially in the over-claimed TMK to produce the product from which profits are to be shared.

The first framework – granting source communities an exclusive right to conduct bioprospecting – has two key advantages when compared to the right to share benefits. First, it gives the right holder a veto power over bioprospecting and thus, forces users to seek a license in advance. This will in turn make the process of enforcing the right much easier compared to a framework that adopts the right to share benefits. In the latter case, since users can use TMK in the publicly available database without the consent of source communities, it may be challenging to identify and locate users. Anyone can access the publicly available database, use it to produce a product, and claim to have not relied on the TMK. To mitigate the problem a presumption could be put in place in which any user who begins conducting research related to a TMK after the publication of the TMK in a publicly accessible database would be presumed to have had access to such TMK. Users will have the burden of proving that they started to conduct research before the TMK publication and/or that they did not ‘substantially rely’ on the disclosed TMK in producing the product. Second, the exclusive right can be licensed on an exclusive basis, and therefore potential exclusive licensees who could earn monopoly rents downstream would share them with right holders. The prospect of earning higher profits from exclusive licenses could be expected to encourage more investment in TMK codification.

Despite these major advantages, the exclusive right to conduct bioprospecting involves the risk of over-claiming discussed above. Furthermore, such framework may lock down wide areas of research by giving an exclusive right to conduct research in such area to one entity. The second framework in which source communities have a right to share benefits enables competition among researchers in a particular field. It also avoids the requirement of locating and requesting a license from source communities, which may be attractive for users. The absence of this requirement may facilitate innovative activity based on the TMK, as has been argued by Reichman.\textsuperscript{542} Although both frameworks have advantages and disadvantages and policy makers could choose a suitable framework, the second framework in which source communities have a right to share the profits

\textsuperscript{542} Reichman \& Lewis, supra note 5; Reichman, supra note 233.
of a successful bioprospecting process is preferred in this dissertation. This will highly reduce the incentive to over-claim and can be expected to facilitate investment and innovation in bioprospecting projects.

**Rights in Restricted TMK Databases:**

With regard to TMK codified in a restricted database, source communities would have the exclusive right to license the TMK and a right to obtain compensation from users who access the TMK through ‘unauthorized’ means.\(^{543}\) Once the source community (or its representative) registers the TMK in a restricted database, individual members of the community will be barred from communicating the registered TMK without the consent of the community elders. Users who induce a member to disclose the information or who violate the rules of obtaining access would be liable for unauthorized access. Information relating to the rules and principles that should be followed to receive a license from the community should be documented together with the TMK.

The various remedies at the disposal of courts could be used to respond further to the particulars of infringement cases that may arise from the proposed bioprospecting right. As the Supreme Court of Canada held in *Cadbury Schweppes Inc v. FBI Foods Ltd.*, the primary objective of calculating the proper mode of compensation in breach of confidential information cases is to arrive at an equitable result given the facts of the case rather than a specific amount of compensation.\(^{544}\) The Court declared that because of the way the common law in developed in the area the suitable remedy for a particular case could emanate from equity, contracts, torts and property.\(^{545}\) These remedies may include accounting for profits, potential royalty fees that would have been paid, lost opportunity, head-start (spring-board) compensations, and even injunctive relief in the limited cases in which other remedies may not result in a fair outcome. For instance,

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\(^{543}\) The right to obtain compensation could be facultative. If a malicious intent is discovered in accessing TK, the amount of compensation could accordingly be higher. This would be decided by the court, tribunal or government agency that would deal with compensation.  


\(^{545}\) *Ibid.*
since most knowledge holder communities may not themselves be engaged in bioprospecting initiatives there may not be sufficient evidence for damages calculated as lost profits. In these cases, adopting the ‘head start’ or ‘springboard’ principle adopted in the Schweppes case may be beneficial. If courts adopt such principle, the damage will be the value of the head-start benefit the defendant received (i.e. the amount of financial expense the defendant saved by accessing the TMK unlawfully).

The World Intellectual Property Organization (WIPO) has developed a robust classification which speaks to the different levels of diffusion entailed in traditional knowledge and the different potential rights that are available.\(^{546}\) Depending on the particular policy objective, the adoption of a mixture of the proposed framework with the classifications outlined by the WIPO may be beneficial.

**WIPO’s Draft Framework**

The WIPO has grouped the potential states in which traditional knowledge may be found and the possible alternative rights that knowledge holders might be interested in (table reproduced below). Such mechanism could be modified for use in the bioprospecting rights outlined in this chapter to meet the needs of the jurisdiction considering adopting the mechanism.

On the ‘nature of knowledge’ column, the tool categorizes traditional knowledge progressively from the least publicly available to the most publicly available. The categorization lists secret knowledge, closely held knowledge, publicly available knowledge, and widely diffused knowledge. With respect to the possible rights that knowledge holders might receive, the tool provides a menu of rights which includes exclusive property rights, moral rights,\(^ {547}\) protection

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\(^{547}\) Moral rights refer to the non-economic right that an author of a copyrighted work has over the work. These rights include the right of attribution, the right to the integrity of a work, and the right to publish a work
against unfair competition and compensation or benefit sharing. At times, the nature of the knowledge might guide the right that best fits the knowledge. For example, an exclusive property right for widely diffused knowledge might be unworkable. Similarly, compensation or benefit sharing might not be an alternative for spiritually or culturally important knowledge that communities are not interested in commercializing. While WIPO’s draft framework outlines the different scenarios, it does not suggest any particular right for any one level of diffusion.

<table>
<thead>
<tr>
<th>Nature of TK</th>
<th>Secret</th>
<th>Closely held</th>
<th>Publicly available</th>
<th>Widely diffused</th>
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</thead>
<tbody>
<tr>
<td><strong>Nature of rights</strong></td>
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<tr>
<td>Exclusive property rights</td>
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<tr>
<td>Moral rights</td>
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<tr>
<td>Unfair competition</td>
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<tr>
<td>Compensation/benefit sharing</td>
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Table 1: WIPO’s Draft Framework for TK Protection

2.4.2 Term of Bioprospecting Right

As stated at the beginning of this section, the second factor affecting the scope of a right is its length. The terms of bioprospecting right should depend on the type of TK database. In the case

anonymously. Moral rights originated in the civil law legal system and, although limited, are recognized in common law legal systems.
of TK documented in a restricted database, protection should last as long as the conditions for protection continue to exist. As long as the TK remains secret and the TK holder community does not document it in a publicly accessible database, there should be a bioprospecting right in such TK. If the TK holder community decides to move TK from a restricted database to a publicly accessible one, then the calculation of term limits should begin from such time. In cases where TK holding communities discloses the TK before it is included in the restricted databases or it discloses without confidentiality restrictions, the source community should still have rights in the restricted TK so long as the core requirements of the proposed bioprospecting right are met.

One implicit requirement is that protection of TK documented in a restricted database would only last as long as the community that documented it. If the TK holder community disappears, then TK documented in a restricted database should be made freely accessible. In order to determine when a TK holding community has seized to exist, the database could require the registration of a contact person or representative of the source community. In cases where no community representative claims rights to the documented TK within a reasonable amount of time, rights in the documentations could seize to exist.

With regard to TK documented in a publicly accessible database, there should be some sort of term limit that begins from the time the knowledge is officially documented in the database. Although some stakeholders call for perpetual rights over TK, economic efficiency would call for the term of the proposed right to be limited to a term that would encourage the optimal codification and disclosure of TMK. Since the effect of legal intervention to encourage codification can only exist as long as knowledge holder communities continue to exist, efficiency requires that the exclusive right should, at a maximum, lapse when the knowledge holder community disappears. However, the exact term can only be determined after considerable theoretical and empirical research into the range of incentives needed to encourage optimal codification of TK. Until a jurisdiction is able to ascertain the optimal term for a bioprospecting right, it should provide such right on an experimental basis based on general references to the

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diverse terms of conventional and unconventional IP rights. It may be argued that in such situations there is a risk that a source jurisdiction might have a lengthy or perpetual bioprospecting right. However, since adopting a perpetual or lengthy bioprospecting right would discourage users from engaging with such jurisdiction, countries might have an incentive to avoid highly restrictive system.

The core question policy makers should take into consideration is the effect that a term might have in encouraging TMK codification and disclosure. If a term is too short it may fail to encourage knowledge holder communities to codify their TMK. If the term is too long, it may discourage users (who would have to pay royalty fees for duration of the term of the right) from using TMK in bioprospecting projects. The appropriate term for TMK should be one that strikes a balance between these extremes. It is reasonable to presume that the longer the term of protection the stronger the effect of the right in encouraging TMK codification and disclosure. However, the incremental effect of an additional year of protection will diminish as the term is increased.

The purpose of establishing the bioprospecting right is to encourage the codification and disclosure of TMK. However, as often noted in this thesis, knowledge holder communities are widely divergent in background and interests. As a result, the amount of protection that would encourage one community to codify and disclose its knowledge might not have the same effect on another community.

It is also worth reiterating that the term of the right is only one factor in the overall scheme of encouraging TMK codification and disclosure. The breadth of the right and other features of the system are essential to the incentive analysis. A framework for TMK protection should take into consideration the cumulative effect of these diverse features in encouraging documentation and disclosure.

Although most economists recommend term limits for intellectual property rights there is little evidence to indicate the optimal term for intellectual property rights in general. In most countries standard patent terms are for 20 years from the date of the application for a patent. In countries recognizing utility models (otherwise known as petty patents) there are diverse but smaller terms (usually 7 - 10 years) that are adopted for small improvements. This implies that the optimal term for patent protection depends on the subject matter of protection. Therefore, it may be worthwhile to investigate the efficiencies involved in differing terms for different TMK contributions to bioprospecting.

In analyzing different terms of protection, policy makers should consider the administrative costs involved. To make an analogy with patents, the optimal system would be one that assesses the life of a patent on a case by case basis - but the administrative costs would make such system inefficient. Similarly, a case-by-case analysis of optimal protection for TMK may be inefficient.

2.4.2.1 Factors Necessary for Setting the Term of Protection

Even if the goal of setting the optimal term of the proposed right is elusive, there are core features that should be considered when determining the duration of a term. Therefore, instead of picking a specific term for TMK this section discusses the core factors that should be considered in selecting such term.

550 Ibid.
551 Robert Cooter & Thomas Ulen, Law and Economics (Boston: Pearson/Addison Wesley, 2008) at 131; See also, Posner, supra note 289 at 59.
553 Cooter & Ulen, supra note 551 at 131.
554 Reichman & Lewis, supra note 5.
555 Cooter & Ulen, supra note 551 at 132.
One core factor to consider is the incentivizing effect that patent law has had on the codification and disclosure of ‘modern’ inventions. Reichman and Lewis suggest that the term “should be longer than we envision for present-day sub-patentable innovation” because of the unique equity goals that are present in the use of the knowledge of indigenous and local communities and “of the typically slow accretion” of such knowledge. By ‘sub-patentable innovation’ Richman and Lewis are referring to improvements on existing knowledge that are not advanced enough to receive patent protection. Both the equity and accretion rate rationales seem to have some force and have implications for the incentive to codify and disclose. Communities that have been oppressed for generations might require a stronger right in order to undo centuries of mistrust. The limited value that TMK has on its own also points to the need for longer a right if it is to be sufficient to encourage the documentation and disclosure of TMK.

Although Reichman and Lewis do mention the term of 20 years in the hypothetical they use they avoid suggesting what the term should be. In most countries, present day sub-patentable innovations such as petty patents or utility models receive protection for 7 – 10 years. The Trade-Related Aspects of Intellectual Property (TRIPs) Article 38 allows member countries to provide protection for up to 15 years for ‘layout designs (topographies) of integrated circuits.’ Because of the low stand-alone value of TMK, it seems that the term of protection should indeed be longer than other sub-patentable innovations that do have a readily available commercial value.

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556 For a detailed discussion of how patent laws encourage the codification and disclosure of “modern knowledge,” See generally Burk, supra note 239.
557 Reichman & Lewis, supra note 5 at 359.
559 Trade Related Aspects of Intellectual Property Rights (TRIPs) of the General Agreement on Tariffs and Trade (GATT), 15 April 1994 [TRIPs] Article 38 (3).
Another factor that should be considered in deciding what term limits to adopt is the average time it takes to produce a successful drug through the use of TMK. The proposed term of protection should be longer than the average bioprospecting time so as to allow communities and their licensees who invest in the documentation and disclosure of TMK to reap sufficient benefits. Those who invest in the codification and disclosure will receive a limited portion of the profits that would accrue from a successful drug development process. This is because the TMK contribution is usually going to occur in the early stages of development and more R & D investments would be required to produce a successful drug. Therefore, in order for this limited share of the profits to be sufficient to encourage communities to codify and disclose their knowledge, the right would have to cover at least the average time the bioprospecting process takes.

The average time the drug discovery process takes has been estimated to be 12 – 15 years.\textsuperscript{560} This is a general estimate that does not take into consideration the use of TMK in the process. Therefore the use of TMK might reduce such timeline significantly. However, it is not easy to estimate by how much such a timeline would be reduced. More research is required to show what the duration of average drug discovery would be if TMK is used. Despite the uncertainty related to the average time the process may take, the currently available 12 – 15 years estimate could be used as a reference point. It should be noted, however, that the expiration of patent rights before investments in drug discovery are recouped is seen as a major problem in the biopharmaceutical industry.\textsuperscript{561} Therefore, researchers would have to consider a similar risk in case of bioprospecting projects when setting term limits.

\textit{Data and Market Exclusivity}

A third comparable that could be used in setting terms for the proposed bioprospecting right is the terms used for data and marketing exclusivity. Data exclusivity refers to the protection extended


Data and marketing exclusivity terms differ depending on the subject matter and the jurisdiction. For instance, the US Food and Drug Administration (FDA) provides seven years exclusivity to Orphan Drugs (ODE) and five years for New Chemicals (NCE). In the European Union, the term has been harmonized (for applications filed after November 2005) and it is eight years of data exclusivity, plus a two-year general marketing exclusivity and an additional one year of marketing exclusivity if the medical product has a ‘new indication.’ Therefore, the term of exclusivity in the EU can extend to 11 years from the initial marketing approval by the original applicant. In Canada, the term is between six to eight years of data exclusivity depending on specific factors. Up to 31 years of exclusivity can be acquired as the maximum term of exclusivity resulting from the combination of 20 years of patent rights with up to 11 years of exclusivity (at least in the EU). In addition to these general terms of exclusivity, there are particular exceptions for which shorter or longer terms of exclusivity are applied.

This brief survey of data and market exclusivity shows that what policymakers believe to be optimal depends highly on the jurisdictional context and the subject matter in question. Although these terms are related to bioprospecting in that they deal with the drug discovery process, data and market exclusivity come into play in the later stages of the drug development process. Therefore the terms of protections being provided for data and market exclusivity may not be

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564 See section C.08.004.1 (3) C.R.C. c.870 - Food and Drug Regulation, 13 June 2015 [C.R.C. c.870 - Food and Drug Regulation].
justified in the case of TMK used in bioprospecting. Furthermore, the terms of data and market exclusivity may highly depend on the lobbying power of special interest group that successfully lobby governments, which makes existing terms much less useful as a reference. Despite these considerable shortcomings, these terms do still provide important reference points in the absence of data relating to the average time that bioprospecting projects take to the point of marketing a TK-based product or service.

While the above analysis points to a limited term of protection for the proposed bioprospecting right, it is appropriate to engage with the proposal for perpetual rights in TMK that some stakeholders advance.\(^{565}\)

**Perpetual Bioprospecting Right?**

Indigenous and local communities are heterogeneous and therefore have different world views. Some communities may not recognize term limits on their knowledge.\(^{566}\) This seems even more plausible given the fact that TMK is usually considered to be an inherent part of the cultural and environmental aspects of the community. It is considered to be part of the cultural identity of some communities. Therefore, the idea of losing control over the knowledge following the expiration of a set term may be alien to some.\(^{567}\) Losing control does not mean losing the ability to continue to use and practice their knowledge. It only means that communities will not be able to regulate the use of their knowledge by others. However, even in this sense, some communities may not be enthusiastic in codifying and disclosing their knowledge to outsiders who might use such knowledge in ways that offend the community.

This is a major difference from Western practices relating to the protection of know-how. There does not seem to be any Western jurisdiction with a perpetual patent system. Terms differ from

\(^{565}\) *Resource book on TRIPS and development, supra* note 547 at 399.

\(^{566}\) Many developing countries and the African Group call for perpetual rights over TK. See *ibid*.

\(^{567}\) McManis & Teran, *supra* note 82 at 140.
one community to another, but every jurisdiction seems to have term limits. The US Constitution goes to the extent of expressly calling for term limits on such rights. The US Constitution gives Congress the power to enact legislation to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”\textsuperscript{568} [emphasis added] It seems clear from such statements that term limits are inherent in the Western conception of patents. Other intellectual property rights such as trademarks and the protection of secret information do not have specified term limits. Such a right could be considered perpetual so long as certain conditions continue to be fulfilled.

There have been calls for perpetual copyright.\textsuperscript{569} However, such proposals have been strongly criticized for misunderstanding the nature of intellectual property rights.\textsuperscript{570} The case for perpetual intellectual property rights is harder to make particularly in the case of patent rights. The scope of patents is generally broader than that of copyrights and thus, making a case for perpetual claims to broad rights is unpersuasive.

As defined in this thesis, TMK is know-how and, as such, resembles subject matter protected under patent laws. As a result of the above-described difference between the world views of indigenous and local communities on the one hand and Western perspectives on the other, a tension might arise when jurisdictions set up the proposed bioprospecting rights regime. It will be a challenge to show an economic efficiency rationale for perpetual bioprospecting right. Presenting moral rights as analogous to a right which at its core is an economic right would be flawed reasoning. The analysis, instead, would benefit more from analogies with other intellectual property concepts.

\textit{Analogy to Database Protection}

\textsuperscript{568} The Constitution of the United States, supra note 212.
\textsuperscript{570} Lawrence Lessig “Against perpetual copyright”, online: \textit{Lessig Wiki}. 
It is plausible to provide renewed protection for new entries into TMK databases. Such a system is all the more important given the need to establish dynamic databases to reflect the dynamic nature of TMK. One key precedent that knowledge holder communities can turn to is database protection. Separate protection for databases – or a database right – is uncommon. Yet, making comparisons between such systems and the proposed bioprospecting right may be fruitful since TMK codification and disclosure would, in effect, mean the establishment of a TMK database.

The European Union database directive is one of the more popular systems of database protection. The core purpose of the EU database directive is economic efficiency. It is intended to correct the market failure that results from the non-excludable nature of information goods documented in databases. Article 10 of the directive sets fifteen years as the term limit for the protection of databases. The directive goes further to state that:

*Any substantial change, evaluated qualitatively or quantitatively, to the contents of a database, including any substantial change resulting from the accumulation of successive additions, deletions or alterations, which would result in the database being considered to be a substantial new investment, evaluated qualitatively or quantitatively, shall qualify the database resulting from that investment for its own term of protection.*

Adding substantially new content to a database gives rise to a new term of 15 years for such databases. Therefore, a dynamic database would have continued protection for substantially altered content. It is possible to apply such a practice to the proposed *sui generis* TMK system. This way, continued protection for dynamic TMK databases would be allowed so long as the information is substantially altered. However, such analogy

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572 Ibid, preamble, paragraph 7.
573 Ibid, article 10 (3).
574 Carvalho, supra note 3 at 261.
will only support continued protection for TMK databases to a limited extent. Some TMK might not change significantly in such a short period of time, and thus, it might not be considered ‘substantially new.’ Additionally, the protection of TMK should be for the benefit of those who provide the information rather than for the benefit of those who ‘own’ or ‘run’ the database. Consequently, the benefits of comparing TMK databases to existing database protection should be complemented by features that address the differences between the two subject matters.

*Analogy to ‘Domaine Public Payant’*

The issue of “domaine public payant” or ‘a paying public domain’ is yet another existing system that scholars have discussed.575 It bears some resemblance to the interest of some knowledge holders for perpetual rights. The *domain public payant*, which mostly relates to copyright law, is a system in which users pay for works that have already fallen into the public domain.576 In 1980 the United Nations Educational, Scientific and Cultural Organization (UNESCO) conducted a survey of its member states asking if they had a system resembling the ‘domain public payant’ in their jurisdictions and 46 members responded.577 Of the 46 countries that responded, a minority (12 countries) confirmed that they had systems that resembled a paying public domain.578 This obligation to pay for public domain material is a perpetual obligation in almost all these jurisdictions579 and takes the form of a small percentage of the selling price of the product.580 It should be noted, however, that some jurisdictions have a short list of the types of works covered under such system. The royalties collected through such a system are either paid directly to

575 Reichman & Lewis, *supra* note 5 at 362.
576 Lewinski, *supra* note 227 at 84.
578 Ibid.
579 “With the exception of Bulgaria, where the domain public payant endures only for 20 years after the work has fallen into the public domain” it is “perpetual, which means, for example, that the users of even the works of Shakespeare or Moliere must pay a royalty” see United Nations Educational, Scientific and Cultural Organization, *Domaine Public Payant* (UNESCO/DA/7) (1949).
580 Ibid (most of the jurisdiction adopt a royalty rate in the range of 2 - 10 % of the selling price of the product.)
associations of authors of works or to the state which, in turn, forwards at least some of the payment to such associations. The application of a paying public domain to traditional knowledge\textsuperscript{581} that has already fallen into the public domain is supported by some scholars, and has already been adopted by some developing countries.\textsuperscript{582}

However, setting up a perpetual right for compensation from know-how raises complex efficiency concerns. The move from protecting expressions perpetually to protecting know-how perpetually has its challenges. First, even if the precedent of a perpetual ‘right’ for compensation exists, it is known only in a handful of jurisdictions\textsuperscript{583} and the right relates only to expressions. Secondly, rights over expression (such as copyrights) are relatively shallow because there are alternative ways of expressing the same idea. Patents rights are broad because acts of infringement do not have to be exact imitations. The doctrine of equivalents allows courts to decide that an act ‘substantially similar’ to the patented invention infringes if it does ‘substantially the same function, in substantially the same way, to yield substantially the same result.’\textsuperscript{584} Acts that are substantially similar to those stated in the patent claim would be considered infringements. Inventors who develop an invention independently (without accessing a patented invention) and those who reverse engineer products embodying an invention are still excluded from receiving patent rights over the invention. The subject matter of protection discussed in this dissertation resembles those protected under patent rights, not copyrights. Even if there is a precedent for granting perpetual rights over expressions, extending such right to know-how is quite different. Additionally, even if the lengthier term of copyright protection (life plus 50 or 70 generally and 95 – 120 for works for hire) exist, proposing such a term for the bioprospecting right is unjustified for the reasons stated above in our discussion of the difference between the two rights.

\textsuperscript{581} As stated at the beginning of Chapter One, ‘traditional knowledge’ is broadly defined by some scholars to include traditional cultural expressions.

\textsuperscript{582} Lewinski, \textit{supra} note 227 at 84; Reichman & Lewis, \textit{supra} note 5 at 358.

\textsuperscript{583} UNESCO/WIPO, \textit{supra} note 54.

\textsuperscript{584} See generally \textit{Warner-Jenkinson Co. v. Hilton Davis Chemical Co.}, \textit{supra} note 534.
There is little literature that shows the efficiencies of adopting a perpetual economic right over know-how.\textsuperscript{585} The risk of establishing an inefficient system is even more pronounced when the right granted is substantively broad. The broader the right the shorter the term should be. Given the fact that the right outlined in this section is a substantive one, it should not be a perpetual right.

One way to respond to this complex question in the context of the bioprospecting right proposed earlier is to set up an inverse relationship between the length and the breadth of the bioprospecting right. The broader the right the shorter its term would be, and the narrower the right the longer it would be. If such a system is adopted, perpetual rights would be left only to the narrowest bioprospecting rights. One may argue that perpetual rights should only apply to ‘moral rights’ in TMK such as the right to receive attribution. Even in such a case, perpetual rights are not warranted because knowledge holder communities might disappear or change so drastically no member could reasonably claim relationship to the community that codified and disclosed the TMK. Therefore, the longest any right should last is for the period the knowledge holder community continues to exist. Perpetual bioprospecting right over TMK is unwarranted in the economic terms discussed in this dissertation.

\textit{Concluding Remarks on Term of Right}

To sum up the discussion in this section, the economics literature would suggest that the longer the term of bioprospecting right, the more codification and disclosure is encouraged, but the more follow-on innovation is discouraged.\textsuperscript{586} However, this general principle is limited by the fact that after a certain length the incentivizing power of protection disappears while the social cost of restricting access continues to exist. Therefore, the incentivizing effect of the proposed right will cease to exist after a certain term. There is little agreement on what the optimal term of exclusive rights over information goods should be. The right term would balance the two interests in static

\textsuperscript{585} Posner, \textit{supra} note 289 at 61.
\textsuperscript{586} Nordhaus, \textit{supra} note 549 at 76.
and dynamic efficiency. Even if there were no dynamic costs (i.e. negative effects on follow-on innovation), the static costs such as higher prices may be greater than the benefit if the right is perpetual.

It seems reasonable to provide protection that is longer than that given to sub-patentable protection (i.e. 7 – 10 years) given the limited standalone value and slow accretion rates for TMK. It also seems justifiable to provide protection for as long as the average bioprospecting process takes. Although the average drug discovery timeline with the use of TMK may be hard to estimate, the 12 – 15 year estimate for general drug discovery timeline could be used as a reference point. Additionally, the diverse terms of protection provided for data and market exclusivity should be factored in. In such analysis it should be noted that these terms of exclusivity may work independently of or in conjunction with the exclusivity provided by patent rights. The general terms of data and market exclusion range from 5 to 11 years.

In terms of the range within which policymakers could decide to fix term limits, a minimal protection of 12 – 15 years could be adopted using the average time it takes to develop a drug. At a maximum, any bioprospecting right adopted under such a system should be tied to the continued existence of the knowledge providing community. As one scholar noted “… the duration of protection [should be] linked to the subsistence of the conditions for protection.” The proposals for perpetual bioprospecting rights over TMK may not be justified when seen through an economic efficiency lens. It may be justifiable to provided renewed terms of protection for significantly new additions to the TMK database, as is done in some existing database protection regimes.

The scope of protection under copyright is shallow compared to the proposed bioprospecting right. Thus, it is not reasonable to compare the two terms. However, the lengthier term of copyright protection could be used as a general reference for the maximum range that the

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588 Lewinski, supra note 227 at 521.
bioprospecting right could be granted. Copyright terms differ depending on several factors. The general copyright terms are the life of the author plus 50 – 70 years for natural authors and 95 – 120 years for works for hire (depending on jurisdiction). The comparison that should be made here is to the works for hire. This is because comparisons to works by natural authors will create either a problem in deciding which individual to use as the author; or, if the community is considered to be the author, in having the bioprospecting right extend even after the community has ceased to exist (community plus 50 – 70 years). Considering TMK codification as a process conducted by a legal person gives the flexibility of selecting a term independent of the life of the author.

Because of the challenges of determining optimal terms, further theoretical and empirical research into, among other things, the average time it take to produce TK-based products through bioprospecting projects should be conducted in order to make an informed decision. The core question in such inquiry should focus on the implications of the different in terms of encouraging the codification and disclosure of TMK, on the one hand, and follow-on innovation on the other.

The term of the proposed bioprospecting right works in tandem with other features of the system and its environment. Therefore the implications of the term of protection should be considered in the larger context under which it operates. Perhaps different features, such as the scope of the right and its value to society, could be considered when deciding what term to adopt.

3 Nature and Scope of Codification and Disclosure

As mentioned in the previous chapter, the nature and scope of TMK codification is one area that critics focus on. The argument is that codification of the knowledge would remove the knowledge from its environmental and cultural context, thereby disrupting its original setting. However, such criticism misses the fact that it is possible to provide cultural and environmental context while codifying TMK. The criticism also disregards the fact that knowledge can be codified without limiting the ability of knowledge holding communities to continue practicing their TMK in traditional ways. The core point here is that TMK faces an alarming rate of loss and imperfect
codification should therefore be preferred over oblivion. In this spirit, the following section discusses the scope of TMK codification.

### 3.1 Holistic Codification

Although the nature and scope of TMK codification could vary according to the capacity and culture of knowledge holder communities, it is preferred that codification be holistic. This is to say that an attempt should be made to include cultural, environmental and geographic aspects of TMK when codifying the body of knowledge. In addition to alleviating the concerns of critics of codification, such a holistic approach may actually increase the value of the codification in different ways. First, the cultural and environmental context in which TMK is found may offer some valuable lessons for subsequent users. Since bioprospecting involves significant unknown elements, the more holistic a TMK codification is, the greater the chance that users will be able to develop successful drugs. Second, in addition to the value of TMK codification for modern medicine, the codification might have significant anthropological and historical value.

An important element in making TMK codification holistic is the use of multi-disciplinary teams in the codification process. Such teams should be made up of not only biomedical professionals but also anthropologists, historians, archivists and other social scientists. Through such a system, knowledge codification could have the supplementary value of preserving the culture and environment through text. In addition to multi-disciplinary teams, cutting edge technological developments could be applied whenever possible. For instance, audio-visual equipment could be used to document not only the knowledge but also the setting in which TMK is used. This could include having body cameras or other recording devices on traditional healers and/or their assistants to document the way they pick their resources, the way they deliver treatments, etc. A concern that may arise here is that, in some cultures, it may be offensive to use certain technologies. In such situations, respect should be given to the customary rules and practices so as not to alienate knowledge holder communities.

It should, however, be noted that holistic codification does have limitations. For instance, use of multi-disciplinary teams and technology may increase the cost of documentation. In some cases,
this increased demand for resources could be set off by the increased value (both monetary and non-monetary) of holistic codification. Codification is valuable even if some communities or countries may not succeed in making holistic codification. Since TMK faces an alarming rate of loss, documenting as much knowledge as possible as quickly as possible should be the goal. Once codified, certain knowledge could be updated using dynamic knowledge codification systems.

3.2 Scope of Codification

A broad system of codification is preferred over a narrow one. While narrow TMK codification would provide little information like the name of the resource and its use, broad TMK codification would add details like where the plant resource is located, what time of the year it grows, what the exact steps of extracting the resources are. It would also include supporting documents collected or created by a multi-disciplinary team. Technologies related to knowledge codification, categorizations, geographical location and the like would be used to make the codification more accessible, holistic and dynamic. The broader the scope, the more valuable the knowledge would be.

Here, it may be fruitful to use the hypothetical case presented at the beginning of this chapter. The story of the Fan people and their Goodya plant can help explain what the different levels of codification can look like. A narrow codification of the TMK related to the Goodya plant would document the fact that the plant is used by traditional healers to help people with depression. It might also state the scientific name for Goodya. But that may be all that narrow codification provides.

A broad codification, on the other hand, would attempt to codify as much information as possible given available resources. For instance, it can include the historical and cultural meaning Goodya has for the Fan people. It would specify the location in which Goodya grows, the seasons in which it grows, and describe the ceremony in detail. In addition to Goodya’s traditional and scientific names, the system would include tags and classifications in which the resource falls under. When possible, it can detail the elements of the Goodya mixture.
In addition to such information, a broad codification could have an audio-visual recording of the process of picking leaves and fruits of the Goodya tree and the full ritual including the chanting and the Hammer dance. The design of the clay pot, the face paintings and the ‘garment of wise men’ used in the ritual would also be recorded in detail. Broad codification should also include information on the customary rules of the Fan people related to their knowledge of the Goodya plant and their cultural expressions such as the Hammer dance and the chants. In general, a broad system of codification should provide sufficient information to allow a user to not only investigate the resource but also understand the context in which it is used. It should also make the knowledge accessible to both knowledge holder communities and users.

There are some TMK databases in different countries that could be used as a guide in setting up TMK codification systems. New databases should take lessons from existing databases and attempt to overcome existing limitations. Perhaps the most famous TMK database is the Indian Traditional Knowledge Digital Library (TKDL) discussed in the previous chapter. The next section discusses a real example from a TMK codification in the TKDL that was used in patent prosecution at the Canadian Intellectual Property Office.

### 3.3 Example of Codified TMK: India’s TKDL

India’s TKDL has managed to codify more than 150 books of Ayurveda, Unani, Siddha, and Yoga with close to three million transcriptions. Although the amount of information included in the database is impressive, it is currently only being used defensively to invalidate non-inventive patents. A more proactive use of the knowledge documented in the database, in the sense advocated in this dissertation, seems to have considerable global welfare maximizing potential. The accessibility of these 3 million transcripts to researchers can be expected to result in increased efficiency in the research and development of biopharmaceutical products and services.

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One sample of the information documented in the TKDL might help explain what a broad TMK codification should look like. The TMK in question was used to challenge patent application number CA 02642184 for a “composition containing ginseng and cinnamon” by Goliath Oil and Gas Corporation. Dr. V.K. Gupta, the director of the TKDL, filed several transcriptions from the database under Section 34.1 of the Patent Act, and the submissions were used to challenge the patent. One of the key transcriptions is reproduced verbatim below to help with the discussion.

Title of Traditional Knowledge Resource: Khamira Sandal Alvi Khani

Knowledge Known Since: 100 Years

TKRC CODE: AO1A-1/1331, AO1A-1/1347, AO1A-1/1654, AO1A-1/1720 […]

IPRC Code: A61K 133/00, A61K 35/64, A61K 36/185, A61K 36/30 […]

DETAILS OF PROCESS/FORMULATION:

1. Khamira Sandal Alvi Khani is a therapeutic single/compound formulation consisting of useful parts of following ingredients(s): Santalum album Linn. (sandalwood), Silk Coccon, Onosma bracteatum, Rosa damascene Mill. (pink rose, Rose), Nymphaea alba Linn. (European white water-lily, Water Lily), Cinnamomum zeylanicum Blume (cinnamon), Crocus sativus Linn. (saffron crocus, saffron), Granular sugar

2. Therapeutic composition/formulation is mentioned below:

590 Terence Teoh, Composition Containing Ginseng and Cinnamon (2011).
1 Santalum album Linn. (sandalwood) - 9 gm

2 Silk Cocoon - shredded 9 mg

3 Onosma bracteatum Flower 12 gm

4 Rosa damascene Mill. (pink rose, Rose) Flower 12 numbers

5 Nymphaea alba Linn. (European white water-lily, Water Lily) Flower 24 gm

6 Cinnamomum zeylanicum Blume (cinnamon) Stem bark 2 gm

7 Crocus sativus Linn. (saffron crocus, Saffron) Stigma 2 gm

8 Granular sugar - 210 gm

3. Therapeutic composition mentioned above is prepared as KHAMIRA: It is a semi solid preparation in which a decoction of certain drugs is prepared, sugar is added to make a base (qiwam). Drugs of animal/mineral origin mentioned in the formulation are powdered and added at this time. It is then shaken vigorously with a DABI till it becomes white. In the end, silver/gold foil is added.

4. A composition as described above is formulated as Honey/Sugar based Semisolid preparation.

5. The dose of [the] above mentioned therapeutic composition is 9 gm.
While the last communications on the file show that the patent is in a ‘state of abandonment’ the official administrative status shows it as a ‘dead application.’

The TKDL seems to be somewhere in the spectrum half-way between narrow and broad codification of TMK. It describes the resources used and the knowledge of their use. However, the knowledge codified is very narrow because it does not provide much information about the people from whom the knowledge originates. There are positive lessons that can be taken for use by TMK databases that will be organized in the future. There are also limitations that should be addressed.

Positive lessons from the TKDL

One of the major achievements of the TKDL is its creation of the Traditional Knowledge Resource Classification (TKRC). The TKRC was developed in response to the lack of organization in documenting Indian traditional knowledge, and it imitated the International Patent Classification (IPC). This seems to have helped in documenting Indian TMK. As can be seen in the example above, the database references both the TKRC and the IPC in each transcription. This will be highly useful for users and knowledge holder communities capable of easily locating the resource they are looking for. Other initiatives codifying TMK should consider developing their own methods of classification as the TKRC seems custom-made for Indian TMK. However, such initiatives could still borrow many features of the TKRC in their own categorizations. If the database begins being used in the proactive sense to help researchers discover drugs more quickly, the TKRC will have the added value of collecting related knowledge about a specific disease.

The other major lesson that could be taken from the TKDL is that, despite the fact that the database is available under restrictive licenses for the sole purpose of patent examination, efforts have been made to make the database accessible by, for example, digitizing the database and translating the

\[591\] *Ibid* at 2.

contents to several global languages. The content of the database has been translated into six languages: English, French, Spanish, German, Japanese and Hindi. The fact that the information is documented in a way that enables digital searches is an important element in its accessibility. The transcription of TMK in scientific terminologies and standardized measurement further adds to its accessibility. The codification specifies the types and quantities of ingredients used in creating the mixture of plant resources with brief instruction on how to produce them. This is valuable as it allows users to replicate successfully the traditional ways of producing the mixture. Replicating what others have done is one of the first challenges in bioprospecting projects.\(^{593}\)

*Limitations of the TKDL*

The TKDL has some limitations that initiatives to codify TMK should attempt to minimize. A core limitation is that the database does not take a holistic approach in the way discussed above. The information documented outlines only the types and amount of ingredients used in a resource for TMK in recipe format. It disregards the cultural, historical, environmental and geographic information that should be documented together with the knowledge. As stated above, the value of codified TMK increases with its breadth. Since bioprospecting inherently involves unknown features of the knowledge and resource, the broader a codification, the greater its ability to help direct researchers. Additionally, the documentation of the cultural, environmental and geographic context in which the knowledge has existed will promote other initiatives such as cultural and environmental preservation.

\(^{593}\) Christina Lee, “AncientBiotics - a medieval remedy for modern day superbugs?”, (March 2015), online: <http://www.nottingham.ac.uk/news/pressreleases/2015/march/ancientbiotics---a-medieval-remedy-for-modern-day-superbugs.aspx> (Discussing how the detailed description of an ancient medicine in a book helped modern scientists replicate its production). Also, the fact that reproducing the work of others being one of the first challenges before discovery was mentioned in personal communication with Dr. Jayson Parker, Lecturer in medical biotechnology in the Department of Biology and Institute of Biomaterials and Biomedical Engineering at the University of Toronto.
The other major limitation of the TKDL is that it is currently only being used defensively to help in invalidating non-inventive patent applications or in limiting the scope of patent claims. Access is granted to patent examiners through restrictive non-disclosure agreements called ‘access agreements’ signed between the Council of Scientific and Industrial Research (India) and the accessing patent offices. India has entered into access agreements with the European Patent Organization (EPO), the German patent office (DPMA), the United States Patent and Trademarks Office (USPTO), the United Kingdom Intellectual Property Office (IPO), the Canadian Intellectual Property Office (CIPO), Intellectual Property Australia (IP Australia), the Japanese Patent Office (JPO), the Indian patent office (CGPDTM) and the Chilean patent office (INAPI). There are slight differences in the restrictiveness of each access agreement. For instance, the first access agreement signed with the European Patent Organization states under the relevant parts that:

Responsibilities and Obligations of User

(i) The User shall not disclose any information of TKDL contents to third parties unless it is necessary for the purposes of the European patent grant procedure in all its phases, including the inspection of files. To this end, the User may, whenever required, deliver information from TKDL contents in whatever form to the patent applicant for the purpose of citations. Except as mentioned above,

594 See Traditional Knowledge Digital Library (TKDL) Access Agreement between the Council of Scientific and Industrial Research (India) and the European Patent Organization, the Japanese Patent Office and the United States Patents and Trademarks Office. (Copy with author)
595 TKDL materials that have been used in patent examination are accessible on the website of the government operated patent search engine. The TKDL licenses state that patent offices may disclose content to third parties when it is required for patent search and examination. At the face of it this phrase seems to allow disclosure only to patent examiners and parties involved in the patent examination process. However, considering the practice of Western jurisdictions in publishing of patent examination material in publicly accessible repositories, the disclosure of TKDL material used in the rejection of patent application to the general public may still be in accordance of the TKDL licenses. Traditional Knowledge Digital Library (TKDL) Access Agreement (with the United States Patent and Trademark Office) See for instance, article 2 (1) - Responsibilities and Obligations of USPTO, in .
the User undertakes to preserve the secrecy and/or confidentiality of the information.

(ii) The User shall use TKDL information only for the purposes of the European patent grant procedure in all its phases including the inspection of files and for no other purpose.

(iii) The User shall on a quarterly basis send the number of times content of TKDL was cited by the User’s examiners during the search process relating to published patent applications.

(iv) Survival of obligations for maintaining the secrecy and confidentiality of TKDL shall remain even after the termination of this Agreement.597

The access agreement with the United States Patent and Trademark Office is slightly more generous in that it allows the USPTO to “publicly post the search result on the USPTO’s Patent Application Information Retrieval System and on other search and examination results digital access systems.”598 This phrase has allowed the USPTO to post the contents of TKDL documentations used in patent prosecution in the US in a publicly accessible manner.599 Despite these differences in restriction, the TKDL’s orientation is defensive and it has a goal of invalidating or limiting non-inventive patent application. The restrictiveness of the database is understandable given the lack of legal protection that encourages proactive use. However, the current state of affairs misses the considerable welfare enhancing potential that a positive use of databases such as the TKDL might bring about. Once there is a satisfactory legal regime that extends legal protection to codified TMK, such databases should be oriented towards positive uses of the knowledge documented in them.

597 Traditional Knowledge Digital Library (TKDL) Access Agreement (with the European Patent Organization) 2 (i - iv). (Copy with author)
598 Traditional Knowledge Digital Library (TKDL) Access Agreement (with the United States Patent and Trademark Office) 2 (i). (Copy with author)
599 Devindra Ramautarsing, Composition for the Treatment of Diabetes Mellitus and Metabolic Syndrome.
4 Implications of Disclosure for Subsequent Patent Applications

In many jurisdictions, if inventors (or individuals who receive knowledge from inventors) disclose an invention to the public before filing a patent, they risk having their patent application rejected for lack of novelty (newness). The disclosure of the invention, even if made by the inventors, would put it in the prior art category, which would bar the disclosed invention from being patentable. An exception to this general principle is found in jurisdictions that recognize grace periods. A grace period gives an inventor a certain amount of time (usually between 6 – 12 months) from the time of the first disclosure of the invention to apply for a patent without affecting the novelty (newness) of the disclosed invention.

Give the above described feature of patent law, a key issue that would arise in the implementation of the proposed bioprospecting rights is the implications of codifying and disclosing TMK for subsequent patent applications by the TK holders. In other words, should the TMK codified and disclosed by the applicant be used as a prior art against the applicant (TK holder) in a later patent application by the TK holder or would the prior registration give the applicant the privilege of overcoming the novelty and non-obviousness analysis? This is an important question because if TMK codification could subsequently be used against the applicant in a patent prosecution, this feature could dis-incentivize TK holders from TK codification and disclosure. Applicants would, in effect, be submitting evidence that could be used against themselves in their future patent applications. Therefore, the capacity of the proposed sui generis system to encourage the codification and disclosure of TMK by private actors depends heavily on what the effects of disclosure on potential exclusive rights would be.

600 Both the US and Canada provide a one year grace period. See, Patent Act R.S., c. P-4, s. 1., supra note 75 at Paragraphs 28.2(1)(a) and 28.3; 35 United States Code §102 - Conditions for Patentability; Novelty [35 United States Code §102 - Conditions for Patentability; Novelty] at paragraph (b, 1).

601 It should be noted that other applicants would be barred from using the codified TMK and therefore would not be able to apply for a patent on an improvement on the codified TMK until the term of the bioprospecting right lapses.
There are policy alternatives that could adopt a narrow or broad right. A system that prefers a narrow right would adopt the position that any disclosure will be used against the applicant as a prior art reference in a subsequent patent application. Here, the applicant would still have lead time to apply for a patent for an invention based on TMK because of the initial exclusive right the applicant would have been granted. It may be that such lead time is sufficient to encourage TK holder to invest in codifying and disclosing TMK. However, since there might be cases in which such lead time is not a sufficient incentive, adopting a narrow right might have the effect of reducing the impact of the *sui generis* right.

The other extreme is to take the position that the disclosure of TMK in a *sui generis* system would not have any detrimental effect on a subsequent patent application by the same applicant. Adopting such a broad right could be expected to send a strong incentivizing signal to applicants interested in codifying TMK. If the policy priority is to encourage the codification and disclosure of TMK, then granting broader rights could be expected to have greater capacity for encouraging disclosure than a system in which the applicant would be submitting evidence that could be used against the applicant in a subsequent patent application. The former system is advocated in this dissertation because of the need to provide a strong signal to TK holder communities to codify and to disclose TK, thus saving the body of knowledge from loss.

It is worth mentioning that there are various points across this policy spectrum any one of which could be adopted to reflect the particular policy objective of the country adopting the system. It should also be noted that the proposed *sui generis* system does not operate in a legal vacuum. The incentivizing effect of the proposed system depends on other legal and regulatory features of the country in question.

## 5 Building Stakeholder Buy-in

Another important challenge the proposed system will face is in convincing the various stakeholders to agree to the framework. The proposed system has to convince knowledge holders to place their trust in it. It has to build confidence among bioprospectors to invest in the
codification, disclosure and use of TMK. And it has to convince governments to establish the legal framework and support codification.

In many countries around the world, indigenous and local communities have been, and in some cases continue to be, oppressed culturally, politically and economically. Past experiences have forced many communities to be suspicious of outsiders, and for good reason. The success of the proposed *sui generis* system of TMK protection depends on the extent to which this distrust between knowledge holder communities and outsiders can be overcome. In order to establish trust, the framework of TMK protection should enable communities to take center stage in the creation of the framework and other major steps along the way. If the framework empowers knowledge holder communities they would be motivated to codify and disclose their knowledge. Making communities equal players in establishing the framework will help in the trust building process.

One way to empower knowledge holder communities is to give them effective decision-making power with regard to what happens once their knowledge is codified and disclosed. Under a property rights rule, knowledge holder communities would be able to give or refuse consent, or to put conditions on access to the knowledge. Each community may have its own interests that cannot be readily included in any legislation. Thus, one way to make sure that these interests are addressed is to allow communities to refuse consent if they find the offer provided in a proposed licensing agreement insufficient. Terms and conditions of a licensing agreement have the capacity to include economic and non-economic benefits or obligations. While communities that seek to receive benefits from their knowledge could do so, those that prefer to give it away freely may choose not to exercise their rights. Giving communities the power to set terms and conditions of access would convince communities that have non-economic interests or values to buy into the system.

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Bioprospectors are another important stakeholder group. Since some (if not most) knowledge holder communities will not be able to finance the codification and disclosure of TMK, they would need partners who can support them in such an endeavor. The support of the private sector is essential to complement government support, especially in cases where government support is largely lacking. Bioprospectors would be encouraged to partner with knowledge holder communities through the incentive of a bioprospecting right they could benefit from once they enter into an agreement with the relevant community. Additionally, since the confusing state of affairs relating to liabilities for the use of TMK in bioprospecting projects raises the transaction costs involved, a clear framework that sets out the obligation of stakeholders will benefit users as well. The combination of these incentives would encourage bioprospectors to buy into the proposed system.

A core question that may be asked on the user side is, why would user countries agree to set up a legal framework that would further restrict the ability of persons within their jurisdiction to access TMK? The answer to this question goes back to the troubling protectionist trend described in earlier sections. The current practice of gaining access to TMK without sharing any benefits with the knowledge providing communities does not seem to be one that is sustainable in the long term. Provider countries and communities have already started restricting access to their knowledge as a result of the lack of protection. The protectionist trend (and the potential for increasing restrictions on access to TMK) should encourage users (and, more importantly, their governments) to agree to shift to a system that rewards knowledge holders.

Even if users were able to evade these restrictions and access TMK, it might increase the cost of future access to the knowledge since knowledge holders will try to protect it through customary means. On the other hand, providing clear and effective rights to TMK would facilitate access to it, thereby reducing costs associated with using TMK. Here, a race for access might encourage user country governments to compete in setting up such systems with the goal of receiving preferred access to TMK. In conclusion, the proposed system might attract user countries because

603 See Section 2.3 on the ‘protectionist trend’ in Chapter Two.
it would facilitate the use of TMK by individuals, institutions and businesses in their jurisdictions. It is also the more feasible route for the long term access to TMK.

6 Conclusion

This chapter has outlined a legal framework intended to encourage TMK codification and disclosure. It proposes the establishment of a *bioprospecting right* that balances the interest of stakeholders involved. The bioprospecting right is a cluster of rights emanating from bioprospecting activity based on TMK. The right will be granted to source communities that codify their TMK either in a publicly accessible database or in a restricted database to which a government agency or other entity would have access. The chapter discussed two alternative rights for TMK codified in a publicly accessible database, each with advantages and disadvantages. The first alternative is the granting of an exclusive right to conduct bioprospecting activities. The second alternative is a right to share benefits from bioprospecting projects conducted by others. The first alternative grants a powerful right to source communities with the power to veto any bioprospecting projects based on the codified TMK. While such a strong right would encourage investments in the codification and disclosure of TMK, it involves a risk as it may encourage source communities to over-claim. On the other hand, the second alternative, which only grants rights to be share profits, involves lesser incentives to over-claim and may encourage users to engage in bioprospecting projects with less transaction costs. While policy makers are encouraged to adopt the suitable framework for their jurisdiction, the second framework is preferred in this dissertation.

In order to benefit from the bioprospecting right, applicants have to fulfill four core requirements. The requirements are: that the applicant either be the knowledge holding community or a licensee of such community; that licensees sign an equitable benefit-sharing agreement with the knowledge holding community; that the applicant clearly describe the knowledge being claimed; and that the knowledge should not be widely diffused.

The chapter then analyses the length of these rights. While specific term of these rights has not been provided, the chapter examines the key factors that policy makers should consider in
designing the scope of the right. It also provides a hypothetical and actual example of TMK codification so as to help policy makers craft an appropriate protection regime. This chapter then discusses the nature and scope of codification that will be subject to the proposed bioprospecting right. The establishment of a holistic codification that includes the details of TMK and the socio-cultural environment in which it is developed is advocated in this dissertation. The chapter concludes by examining the implications of TK codification and disclosure on subsequent patent applications by TK holders or their licensees. It also examines ways in which the bioprospecting right could build the interest of diverse stakeholders.
CHAPTER FIVE: THE GLOBAL PROTECTION OF TRADITIONAL KNOWLEDGE: STATE OF AFFAIRS, TRENDS, AND SCENARIOS

1 Introduction

The previous chapter outlined a legal framework through which TMK codification and disclosure could be encouraged. The bioprospecting right mechanism is discussed as a framework that could be adopted in domestic jurisdictions. This chapter will, therefore, consider whether domestic protection will be sufficient to encourage the codification and disclosure of TMK globally, or if an international mechanism is needed. The chapter outlines domestic measures that could be adopted to mitigate some of the challenges that the domestic bioprospecting right could face but acknowledges the need for an international framework to realize fully the global welfare-improving potential of TMK.

The chapter analyzes the international instruments and institutions discussing TK protection, with deeper examination on forums most relevant for TMK - the World Intellectual Property Organization (WIPO), the Convention on Biological Diversity (CBD) and the World Trade Organization (WTO). Following these introductory sections, the deliberation of the Draft Articles for TK protection at the WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) will be analyzed in detail. The Draft Articles reflects an advanced discussion of TK protection, and it is unique in expressly encouraging TK codification. Four key issues of contention that delegates have continued to debate will be examined in this regard.

The chapter then examines the minimum substantive standards that should be adopted at the international level to facilitate the cross-border use of TMK. In this context, a few promising proposals that could provide an efficient international protection for TK are analyzed. The ‘disclosure of origin’ requirement has received special attention in recent deliberations on international TMK protection, including at the WIPO IGC. The requirement obligates patent applicants to disclose the origin of TK used in the process of developing a claimed invention. The requirement has a considerable potential for TK codification and disclosure discussed in this
dissertation. Another promising proposal is the international recognition of national laws. This proposal will also have significant implications for solving some of the challenges that domestic bioprospecting rights could face. The chapter concludes with a discussion of the potentials and challenges of using Free Trade Agreements (FTAs) to establish international norms for TK protection.

2 Is an International Protection Mechanism Necessary?

The preceding chapter outlined a framework through which TMK could be protected domestically. However, as discussed in chapter two, TK is a global public good that crosses local and national borders. Therefore, there is a risk of extra-territorial free-riding - firms in countries that do not have domestic TK protection systems could free ride on TK codifications in other jurisdictions that provide protection. If country A has established a TK protection mechanism and as a result has a robust TK database, firms in country B, a jurisdiction that does not recognize TK protection, could access the TK database in country A without being bound by country A’s protection mechanism. This may discourage country B and other jurisdictions from adopting TK protection mechanisms in order to allow firms in their jurisdictions to free-ride on TK codification in country A. Firms in country B, which will not have to share profits with TK holders, would have the advantage of low production cost over firms in country A, which have to share profits. This may discourage country A from adopting a protection mechanism in the first place. This risk of extra-territorial free-riding brings up the question of whether there is a need for international protection or if domestic protection would suffice to encourage TMK codification and disclosure? The implication of territoriality of rights in the system proposed in the previous chapter is an important point. This is especially the case given the non-excludable nature of TMK and the fact that it does not require an advanced level of expertise to understand the knowledge.

One way to respond to the risk of extra-territorial free-riding is to argue that if the major users of TMK adopt the proposed sui generis system, there could be sufficient incentive to codify and

604 Ebermann, supra note 110 at 174.
disclose the knowledge, even if not all countries in the world adopt it. If most developed countries in which most users of TMK reside adopt the proposed *sui generis* framework within their domestic systems, the need for international protection will be reduced. Researchers and firms in developed countries could be required to abide by domestic rules if they use TMK from abroad. Domestic laws could also be recognized in international instruments (a proposal discussed in the final section of this chapter). If TK holders (or their licensees) can recoup their investments on TMK codification and disclosure from the jurisdictions that provide protection, they might continue to invest in such endeavors despite the lack of protection in some countries.

However, most key jurisdictions in the Global North, including those with considerable indigenous populations, have not adopted a TMK protection mechanism. Almost all domestic legislation\(^{605}\) and all regional frameworks\(^{606}\) on the TMK protection are in countries and regions that seem to be net exporters of TMK and genetic resources. Furthermore, such response to extra-territorial free-riding may not adequately address the situation described above where firms in countries that do not protect TMK could have an advantage over firms in countries that do protect it. This risk might convince countries to avoid protecting TMK, ultimately challenging the effectiveness of the regime.

Another way to respond to the problem of free-riding on the international stage is to either make the codified TMK confidential or defer its public disclosure. Making codified TMK confidential for a limited amount of time would give applicants in the *sui generis* system lead time that could support them in recouping the investments they make in codifying and disclosing TMK. Competing firms in other countries would not be able to free-ride on the knowledge for at least some period of time. This delayed access might, in turn, encourage countries to establish TMK protection mechanisms in order to gain preferred access to it. It should be noted here that countries

\(^{605}\) A search query for “Traditional Knowledge” in the WIPO Lex (a search engine for relevant legislations) lists domestic legislations relevant for TK. “WIPO Lex Search (Query: Traditional Knowledge (TK))”, online: <http://www.wipo.int/wipolex/en/results.jsp?countries=&cat_id=18>.

that have many indigenous peoples and local communities would have an incentive to establish a system of protection for self-serving reasons.

There are current practices of deferred disclosure upon which such claims could be based. Under the patent laws of some developed countries, patent applications are not disclosed to the public immediately. For instance, in the US and Canada, patent applications are published to the public 18 months after the application date. Within this confidentiality period, the patent application and documents submitted with the application are not accessible to the general public. In the wider academic research community, although the priority is to make research reports freely accessible, there is the culture of putting embargoes on research reports in exceptional circumstances. The purpose of deferred disclosure seems to be to protect the inventor or author of the knowledge from unfair competition with others who might use the disclosed knowledge. A similar argument for deferred disclosure can be made in the case of TMK disclosure.

If confidentiality and deferred disclosure mechanisms are adopted, at least some of the risks associated with extra-territorial free-riding will be addressed. The competition to get preferred access to TMK could be sufficient incentive to induce countries to provide protection. However, such approach is not the optimal mechanism because it will restrict the dissemination of valuable knowledge. Additionally, given the ‘global public good’ nature of TMK and its cross-border use, the territoriality of any proposed TMK protection could seriously undercut its effectiveness. As stated in preceding chapters, while countries of the Global South hold the lion’s share of TMK and related genetic resources the Global North is where the intellectual and financial capacity to exploit such resources resides. Thus, there are major contributions that an international system of TMK protection could make.

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608 Office of the Governing Council, University of Toronto Publication Policy (University of Toronto, 2007) (In addition to some restrictions on publications by faculty and staff, graduate student are also able to put a temporary embargoes to restrict a library from putting a copy of their thesis in its database).
609 Ebermann, supra note 110 at 174.
In a workshop organized by the United Nations Conference on Trade and Development (UNCTAD) and the Commonwealth Secretariat on national systems of protection, delegates from various countries highlighted the need for an international system of protection. Some of the more important reasons cited for the need to establish international protection include the need to have domestic legislation of one country implemented in another; the need to respond to restrictions that states face from Article 27.3(b) of the TRIPs article; the need to stop the patenting of traditional knowledge sourced from a foreign jurisdiction; and the challenges of the monitoring and enforcement of violations in foreign countries.

In addition to the reasons highlighted by country representatives, scholars have attempted to extrapolate the challenges of international protection from failed past experience and the concerns of stakeholders. Intuitively, it seems to makes sense that relationships between actors located in different corners of the world that cross various jurisdictions be governed by a supra-national mechanism. As rightly noted by Jane Anderson, an international protection mechanism could function as an “overarching authoritative framework for negotiations” for parties involved in bioprospecting. This may include a supra-national dispute settlement mechanism in order to avoid the influence of politics on the bioprospecting process. The unequal power that exists among countries and between TK users and knowledge holding communities is another key reason for the establishment of an international mechanism on which such relationships could be built.

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611 Article 27.3 (b) of the TRIPs agreement requires that jurisdictions bound by the TRIPs agreement must provide protection for some life forms “either by patents or by an effective sui generis system.” Delegates at the UNCTAD-Commonwealth Secretariat workshop felt that, while the exclusion of all life forms would have been an effective tool to stop biopiracy, because Article 273 (b) requires such protection for some life forms member countries did not have the flexibility to ban patents on life forms. See, *ibid.*


614 Oguamanam, *supra* note 606 at 165.
Currently, there are different international instruments and organizations relating to the protection of TK. However, they have yet to provide clear and holistic protection.\textsuperscript{615} While most of the instruments have no express statement on TK codification and disclosure, some of them consider TK codification to be a key part of the attempt to provide TK protection. The most promising and comprehensive attempt to protect TK is taking place in a committee of the World Intellectual Property Organization (WIPO). The ‘Draft Articles on the protection of traditional knowledge,’ the most advanced instrument on TK protection, is being negotiated at the WIPO. Although TK codification is not a prerequisite for protection, the need to encourage TK codification has been highlighted in this framework and delegates seems to have reached a consensus on the matter. Before examining the Draft Articles, the following section outlines the various international dialogues on TK protection, including a general overview of the process at the WIPO.

3 The Protection of TMK under International Law

Traditional medicinal knowledge lies at the intersection of multiple issues of international governance and is, therefore, being discussed in multiple forums.\textsuperscript{616} It involves global public health issues because a considerable portion of the world’s population relies on TMK and its exploitation could impact the health of a significant portion of the world’s population.\textsuperscript{617} A considerable proportion of drugs are produced from genetic resources so TMK discussions have implications for both biodiversity conservation and environmental protection.\textsuperscript{618} The uses of TMK in internationally traded drugs have given rise to discussion in trade and development circles. Given the historical and continuing oppression of indigenous peoples and local communities, the issue also touches on the field of human rights. Advancements in biotechnology and other technological areas, the international pressure for the conservation of biodiversity, movements for the recognition of indigenous peoples and local communities all have contributed

\textsuperscript{616} UNCTAD, Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices (TD/BCOM.1/EM.13/2) (UNCTAD, 2000) at 6.
\textsuperscript{617} See generally, Fabricant & Farnsworth, supra note 96.
\textsuperscript{618} See generally, Tomlinson & Akerele, supra note 113.
to the current state of affairs. While the CBD and WTO deliberations do not specifically refer to TK codification or disclosure, the WIPO IGC has facilitated substantial discussion focusing on the need to save TK from loss through documentation. Thus, while the discussion in Section 3.1-3.4 is intended to introduce the core forums for TK protection, the implication of WIPO’s work related to TK codification and disclosure will be examined in Section 4.

3.1 World Intellectual Property Organization (WIPO)

International discussions related to TK began in the 1960s when countries in the Global South began calling for the recognition of the contributions of traditional cultural expressions. This movement managed to produce the WIPO-UNESCO (United Nations Educational, Scientific and Cultural Organization) Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Forms of Prejudicial Action in 1982. The model provision allowed countries interested in protecting folklore to voluntarily use the Model Provisions in crafting domestic legislation. In addition to the Model Provisions, the movement to protect folklore managed to have the rights of performers of folklore recognized in the 1996 WIPO Performances and Phonograms Treaty.

However, these early discussions of the protection of folklore focused on cultural expressions and not traditional knowledge *stricto sensu* as defined in this dissertation. International discussions on the protection of TK *stricto sensu* began as part of the movement for biodiversity conservation and were affected by technological advances, especially in the biotechnology field. A key instrument in this initiative is the Convention on Biological Diversity discussed in the next section.

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620 *Ibid* at 1.
The work of the WIPO on the intellectual property issues in genetic resources and traditional knowledge began in the late 1990s. In preparation for the Patent Cooperation Treaty (2000), member states of the WIPO brought the issue to the Standing Committee on Patents and gave their first mandate for the organization to take up issues related to TK in 1998.\footnote{\textit{Ibid} at 2.} WIPO undertook nine fact-finding missions throughout 1998 and 1999.\footnote{World Intellectual Property Organization, \textit{Intellectual Property Needs and Expectations of Traditional Knowledge Holders}, Mission Report (Geneva, 2001).} This was an attempt to collect first-hand accounts of the ‘intellectual property needs and expectations of knowledge holders’ and included consultation with indigenous peoples and local communities, governments, industry representatives and civil societies in several countries. Among other things, the fact-finding mission report highlighted the need to reform existing intellectual property laws and to work on creating new legal tools for TK protection.\footnote{\textit{Ibid} at 8 Executive Summary.}

As a result of discussions that took place around the Patent Cooperation Treaty, member states agreed that there was a need for a permanent forum to discuss issues related to genetic resources (GR), traditional knowledge (TK) and traditional cultural expressions (TCEs).\footnote{World Intellectual Property Organization, \textit{supra} note 619 at 2.} This brought together WIPO’s past work on folklore along with the related issues of GR and TK. Thus, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established in September 2000. The three key features that gave rise to the IGC have been summarized as follows:

… First, it was established to address three new themes that shared certain distinct features: GRs, TK and TCEs were simultaneously regarded as the “common heritage of humanity” and as intellectual valuables requiring appropriate forms of IP protection. Second, GRs, TK and TCEs were seen as the intellectual assets of new key players in IP policy-making, namely developing countries and indigenous and local communities. Third, and more broadly, the IGC was conceived as part of a larger and structured endeavor
by WIPO to move towards a modern, responsive IP system that could embrace non-Western forms of creativity and innovation, be comprehensive in terms of beneficiaries, and be fully consistent with developmental and environmental goals.\textsuperscript{627}

Although other forums have held discussions on TK protection, the IGC has been the key international forum in this regard.

The early years of the IGC (2000 – 2004) were focused on the defensive protection of TK.\textsuperscript{628} After almost a decade of deliberations, member states of the WIPO decided in 2009 that the IGC should begin working towards one or more international instruments that would govern the issues of GR, TK, and Folklore. Deliberations at the committee have at times been highly contentious. For instance, the IGC mandate failed to be renewed in the fall of 2014.\textsuperscript{629} However, the committee’s mandate was renewed in 2015 and it has continued hosting the most advanced discussions on the protection of traditional knowledge.

Various groups of like-minded countries emerged during the process of the IGC negotiations. A general categorization of these groups shows that most developing countries (especially those with a high concentration of biodiversity and indigenous communities) strongly advocate the international protection of TK while most developed countries prefer to maintain the status quo. Insightful linguistic anthropological research into the IGC negotiation has been conducted by Stefan Groth.\textsuperscript{630} After observing the IGC deliberations and personally conversing with delegates personally on informal occasions, Groth confirms the general divide in positions between the

\textsuperscript{627} Ibid.
\textsuperscript{628} As defined in the first chapter under section 1.7, defensive protection of TK is the attempt to stop users of TK from claiming IP rights by producing evidence of the existence and/or use of TK.
\textsuperscript{630} Stefan Groth, Negotiating Tradition: The Pragmatics of International Deliberations on Cultural Property (Universitätsverlag Göttingen, 2012).
developing and developed countries. He clusters the member country delegates at the IGC into ‘stalling delegates’ and ‘speeding up’ delegates to describe the general orientation of the delegates participating in the negotiation.631 The various groups of like-minded countries include, among others, the African Group, GRULAC (Latin American and Caribbean Group), the Asian Group, Group B (US, JAPAN, New Zealand, EU, and Australia), the Central European and Baltic States, and Central Asian and East European Countries. As can be observed from negotiation texts, developing countries with significant biodiversity resources and traditional knowledge, and those in which a considerable number of local communities reside (especially Brazil, India, Peru and some African countries) are strong demandeurs of TK protection.

However, Groth acknowledges that the clustering of ‘stalling’ delegates and ‘speeding up’ delegates is “an abstraction to characterize far more complex and multilayered processes.”632 He reveals that some developed countries may actually be willing to agree to some form of international TK protection, while still other developing countries may be adopting politically strategic positions by supporting like-minded countries in order to use the political capital gained from such support in other international forums.633 Furthermore, the demandeurs of TK protection are diverse and include developing country governments, indigenous peoples, local communities, NGOs, researchers, international and regional organizations. This diversity results in a diversity of perspectives on and approaches to TK protection. The lack of a consensus among even the demandeurs of TK protection has contributed to the slow progress of the IGC.634

631 Ibid at 42–44.
632 Ibid at 44.
633 Ibid, Groth gives the following example to show how countries support like-minded states in politically strategic ways. “To give an example, Egypt has a notably strong voice in WIPO IGC negotiations on traditional knowledge and folklore. Yet, in private conversation, one high-ranking Egyptian delegate made clear to me that his country has no interest in the protection of TK or TCEs whatsoever – it is not on the domestic agenda, nor does it play a big role in diplomacy. Yet, in negotiations, the Egyptian delegate makes drastic statements and demands, increasing the pressure on the stalling delegations as much as possible. The delegate explained this position by noting that Egypt regards the current UN system as unbalanced and disadvantageous to developing countries. So to increase the pressure on industrialized nations, negotiation tokens from WIPO’s IGC are used to try to bring about changes in the UN system, including in neighboring fora like the WTO or CBD.”

634 The lack of consensus among the advocates of TK protection and the negative impact that it had in the IGC process was confirmed by delegates involved in the deliberations of the IGC in presentations made at a workshop organized by the International Law Research Program at the Center for International Governance Innovation on
Despite the contentious deliberations, the IGC has produced an important document on TK protection – ‘The Protection of Traditional Knowledge: Draft Articles’ [Draft Articles] – which distills the deliberations+ of delegates over the past several years. There are numerous brackets in the document showing terms on which delegates could not agree. Since these brackets are used with respect to numerous key features, future prospects for the Draft Articles are highly unpredictable. Considerable work needs to be done before an international instrument on which member states can agree on is produced. Because of the high importance of this forum to the discussion in this dissertation, the key issues of contention in the Draft Articles and their potential to save TMK from an alarming rate of loss is discussed in Section 4 below.

### 3.2 Convention on Biological Diversity (CBD)

As stated in earlier chapters, the protection of traditional knowledge in general (differentiated from cultural expression) began as part of a larger discussion on the conservation of biodiversity resources. The Convention on Biological Diversity (CBD) is one of the first international conventions to mention traditional knowledge. It is, in fact, the only binding international treaty to expressly call for the protection of such knowledge. However, the CBD has general statements that are aspirational rather than being enforceable on their own.

The global nature of the values of biodiversity and its alarming rate of loss spurred talks and galvanized states to collaborate in the effort to find a global solution. Work on the Convention began in 1988 when the UNEP’s (United Nations Environmental Program) Ad Hoc Working Group of Experts on Biological Diversity was established. As a result of the work of the Ad Hoc Working Group, which included technical (legal) and political negotiations, the Convention was


635 UNCTAD, supra note 609 at 6.
opened for signature at the 1992 Rio “Earth Summit” (United Nations Conference on Environment and Development) and entered into force in 1993.\textsuperscript{636}

The Convention currently has 194 signatories\textsuperscript{637} and is a key instrument in the movement for the protection of TK. Before the CBD, biodiversity resources were considered to belong to humankind in general. However, this position was considered to be one of the causes for the alarming rate of biodiversity and TK loss. Thus, the CBD signaled a change in perspective from one considering biodiversity and related TK to be a ‘common heritage of mankind’ to one considering it to be something over which source countries have rights. In recognizing these rights, the preamble states that the “conservation of biological diversity is a common concern of humankind”\textsuperscript{638} displaying the change in terminology. [Emphasis added.]

Despite the near universal acceptance of the core mission of conserving biodiversity, the details of the Convention and its implementation have proved contentious. As a result, the rights and obligations recognized in the Convention are general and vague. For the purposes of TK protection, the key sections of the CBD include Articles 8(j), 10(c), 15 and 18(4).

These provisions are more aspirational than substantive in that they use qualified language including the phrases “as far as possible and as appropriate” and “subject to national legislation.” Besides, the CBD does not expressly calls for the protection of TK. The most functional of these provisions is Article 8(j)\textsuperscript{639} which states:

Each Contracting Party shall, as far as possible and as appropriate: …

\textsuperscript{636} For historical account of the Convention including the various meetings and related documents see, Secretariat of the Convention on Biological Diversity, “History of the Convention”, online: Convention on Biological Diversity <https://www.cbd.int/history/>.

\textsuperscript{637} Notably, the United States of America has not ratified it.

\textsuperscript{638} Preamble, paragraph 3, The Convention on Biological Diversity, supra note 113. See also paragraph 4 the preamble and article 3.

\textsuperscript{639} Mugabe, supra note 10 at 116.
(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.\textsuperscript{640}

The numerous conditions in the provision show its limitations and its vagueness. The provision reflects some advances since it could be used to create a legal mechanism through which knowledge holder communities and countries could share the benefits arising from the use of their knowledge and resources. However, it permits “backward, exploitive, and even abusive regimes to continue their practices under the banner of ‘national legislation.’”\textsuperscript{641} The need to respond to the local context through diverse national legislation is undeniable in every international regime. However, Article 8 (j) seems completely dependent on the unilateral initiative of members states and on whether or not they prefer to provide TK protection. The consensus after the signature of the CBD is that it does not go far enough in calling for TK protection.\textsuperscript{642}

The other relevant provisions, Articles 10 (c), 15 and 18 (4), are also highly qualified. A combined reading of the articles provides a general obligation for cooperation in the promotion and conservation of biodiversity and the ability of states to craft systems for the sharing of benefits arising from the use of such biodiversity resources and knowledge. All these vague and general obligations are subject to the existence of national legislation.

On the positive side, the Convention is only a first move towards international dialogue on the protection of biodiversity and TK protection. It functions as a framework instrument which

\textsuperscript{640} Article 8 (j), The Convention on Biological Diversity, supra note 113.
\textsuperscript{641} Horton, supra note 84 at 24.
\textsuperscript{642} Mugabe, supra note 10 at 117.
requires additional documents to be implemented. As one of the steps in elaborating on the CBD, working groups and meetings of the Conference of the Parties (COP) managed to produce two instruments: The Bonn Guidelines (2002) supra note 129 and the Nagoya Protocol (2010) supra note 130.

The Bonn Guidelines (on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization) is an important step in clarifying the CBD. It is a voluntary system intended to support member countries in developing legislation and contractual regimes for access to and benefit sharing from the use of genetic resources and TK. The Access and Benefit Sharing (ABS) mechanism has proved to be useful under the Guidelines. Several member states, especially developing and Least Developed Countries (LDCs) have made use of the system and the financial support provided in order to establish national ABS mechanisms. The Guidelines are supported by a central clearinghouse connected to domestic clearinghouses that function as a network of information sharing centers on relevant experiences.

More importantly for the purpose of this chapter, the Guidelines fueled discussion on the requirement of disclosure of origin of source countries/communities in procedural and substantive patent law instruments. The disclosure of origin requirement applies if a patent applicant, directly or indirectly, used a genetic resource or TK in developing the invention being considered for a patent right. The applicant will be required to disclose the source country or community and it is hoped that this mechanism would allow countries/communities to set conditions on accessing such resources. Following the inclusion of such a standard in the Bonn Guidelines, the government of Switzerland led a successful movement to include the requirement in the (procedural) Patent Cooperation Treaty and the (substantive) Patent Law Treaty. supra note 605 at 160. It should be noted that this is one of the few cases in which a developed country has taken the lead in advocating for TK protection in an international forum.
The disclosure of origin discussion is indirectly aligned to TK codification and disclosure discussed throughout this dissertation. Patent applicants who are required to disclose the origin of TK used in a claimed invention will prefer to have a codified and accessible TK database that they could cite to fulfill such a requirement. Therefore, firms that use TK will have a stake in the efficient and systematic documentation and disclosure of TK.

Despite the progress made with the Bonn Guidelines, the focus of the instrument was still on genetic resources. Additionally, the fact that the guidelines are voluntary appears to have limited their success in protecting TK. Consequently, at the 2004 Conference of the Parties (COP) meeting of the CBD, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing was mandated by member states to work on an instrument that would elaborate on Articles 8(j) on TK and Article 15 on Access and Benefit-sharing. The resulting document, the Nagoya Protocol, was adopted on October 29, 2010, following six years of intense deliberations and came into force on October 12, 2014. The purpose of the protocol is to provide legal certainty and clarity in implementing the CBD’s third objective – access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. To make the Access and Benefit Sharing obligation effective, the protocol requires that signatories ensure the establishment of checkpoints as compliance measures and the availability of domestic remedies.

Several parts of the protocol were controversial including the binding nature of the protocol and its implication for TK protection in general. The protocol will be binding on the states that have ratified it, and this is one of the key improvements that the protocol has brought about. Other highlights include Global Clearing-House and Multilateral Access and Benefit Sharing mechanisms. Although the protocol’s recognition of customary laws of indigenous people and

646 The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity, supra note 131 Introduction.
647 Ibid See articles 14, 17, 18.
648 Wallbott, Wolff & Pozarowska, supra note 203.
649 There are currently 66 parties to the Protocol and 92 signatories. It is expected that all signatories will ratify the protocol. Secretariat of the Convention on Biological Diversity, “Parties to the Nagoya Protocol”, online: Conv Biol Divers <https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>.
local communities on biodiversity and TK is a step in the right direction, it subjects such laws to domestic laws of signatories. The protocol also defers to other international instruments and deliberations which might reduce its capacity to address issues related to access and benefit-sharing processes. However, the protocol has only been in force for two years. Thus, analysis of its impact will have to be made at a later point once there has been sufficient time for implementation. As the latest in the international attempt to protect genetic resources and TK, the success of the protocol will have a considerable impact on the realization of the potential that TK holds. Since most of the user countries have not yet ratified the protocol, there is much to be done before the objectives of the protocol will be met.

TK protection as an independent issue has been a contentious topic in Nagoya Protocol deliberations. Since the focus of the Convention and discussions has been the conservation of biodiversity resources, TK has been discussed only in so far as it relates to this core objective. TK was not discussed as a standalone issue which seems to have been a result of the historical development of the CBD framework. As stated earlier in this chapter, a discussion of standalone TK protection began at the WIPO, and the work of the WIPO and other international forums seems to have influenced the Nagoya Protocol negotiation process in reinforcing the need to protect TK. The protocol requires the ‘prior informed consent’ (PIC) of knowledge providers before users access TK and a fair and equitable sharing of profits. As mentioned in earlier chapters, most bioprospecting projects and TMK are based on plant genetic resources. Given the broad scope of the phrase ‘associated with genetic resources,’ the Protocol seems to cover most uses of TK in bioprospecting processes. The protocol also requires the fair and equitable sharing of benefits with source communities.

650 Oguamanam, supra note 606 at 163.
651 See article 4, The Nagoya Protocol on Access and Benefit Sharing of the Convention on Biodiversity, supra note 131; Oguamanam, supra note 606 at 163.
652 Oguamanam, supra note 606 at 163.
654 Ibid at Article 5, 6, 7.
The Nagoya Protocol is an essential instrument for the bioprospecting right proposed in the previous chapter. The fact that the Nagoya Protocol, as a mandatory instrument, outlines the principles of PIC and the fair and equitable benefit sharing makes it an indispensable tool for the prospecting right framework, a mechanism which considers these two principles to be a core part of the framework. Jurisdictions adopting the proposed bioprospecting right should use the PIC and fair and equitable benefit-sharing provisions of the Nagoya Protocol when crafting domestic laws.

To sum up, while the CBD is a key instrument for the TK protection discussion it is a general statement that requires more detailed instruments for implementation. The Nagoya Protocol has met some expectations and failed to meet others. The core successes of the protocol include its reiteration of the principles enshrined in the CBD and Bonn guidelines; it inclusion of advances made in supporting the recognition of the rights of knowledge holders and, more concretely, and its establishment of compliance measures such as checkpoints which are essential for enforceable access and benefit sharing mechanisms. The protocol’s shortcomings include its vagueness, the fact that it subjects recognition of customary laws to the laws of domestic jurisdictions and its express deference to other international instruments. The Bonn Guideline and the Nagoya protocol are essential tools for the bioprospecting right proposed in the previous chapter. These instruments provide for the disclosure of origin requirement, the principles of PIC, and the fair and equitable sharing of benefits.

An important and contentious issue that the Protocol failed to address is the interplay between the CBD framework and the global protection of intellectual property covered under the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement. Before discussing this ambiguity it is appropriate to examine the approach of the WTO-governed TRIPs agreement to

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655 Oguamanam, supra note 606 at 163.
657 Oguamanam, supra note 606 at 163.
the protection of TK. The following section discusses TRIPs and how it relates to TK protection followed by a description of the tension between the CBD and the TRIPs regimes.

3.3 Trade-Related Intellectual Property Rights (TRIPs)

During and immediately following World War II, allied powers deliberated on the structure of the global financial and economic system. At the heart of the deliberation was the creation of the “Bretton Woods” institutions – the World Bank and the International Monetary Fund. Several countries wanted to create a third institution to focus on the trade aspect of the framework. The initial attempt at establishing the International Trade Organization in 1948 did not succeed (largely because of opposition in the U.S. Congress) and the General Agreement on Tariffs and Trade (GATT) remained a provisional document until 1994. After more than seven years of negotiation, on 15 April, 1994, ministers of most of the 123 negotiating states signed the agreements establishing the World Trade Organization (WTO) in Marrakesh, Morocco.

The WTO currently claims credit for being the sole institution tasked with facilitating trade on a global scale and boasts of an impressive increase in global trade since the early versions of the GATT were implemented in 1950. A unique feature of the WTO system that distinguishes it from most other international institutions is the effectiveness of its dispute settlement mechanism. However, the mechanism continues to be controversial as it is considered by some experts and member countries to be too intrusive in the sovereign powers of member states.

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659 Ibid.
662 Robert E Hudec, “New WTO Dispute Settlement Procedure: An Overview of the First Three Years” (1999) 8:1 Minn J Glob Trade 1 at 3. (The paper analyzes the 98 cases that were dealt under the dispute settlement mechanism in the first three and half years of its existence.)
663 Hudec, supra note 662 See generally and on page 3.
The Trade-Related Intellectual Property Rights (TRIPs) Agreement which forms part of the WTO agreement is the instrument that outlines the intellectual property rights and obligations of member countries. It represents the first time that an international treaty has provided a “floor for protection in all major areas of [intellectual property rights] and a ceiling for anti-intellectual property right measures.” The TRIPs agreement may be the most controversial area of the WTO system. One of the points of criticism is that it is seen by many as serving the interests of the Global North (or, particularly, IP exporting states) and limiting the policy space for countries in the Global South to consider local contexts. This criticism is acutely evident in the global public health discussions and, more particularly, in the access to medicine debate.

Traditional knowledge, which is dominant in countries of the Global South, is not recognized under the TRIPs agreement. There is a “profound silence around the protection of indigenous and traditional knowledge” in the agreement. It is arguable that TK protection established by a member state in its domestic legal system would be TRIPs-Plus (i.e. a right granted in addition to the baseline protection under the agreement) or outside of TRIPs. If TK protection is TRIPs-Plus, member countries could establish protection under their domestic jurisdiction so long as such protection does not encroach on their TRIPs obligations. If, however, TK protection is outside the TRIPs agreement, then it does not need to be bound by some of the TRIPs terms such as national treatment. The expressed wish of countries from the Global South has been to include TK protection as an integral part of the obligation under the TRIPs Agreement or agreements of similar scope. In response, developed countries seem to have engaged in a ‘regime-shifting’ strategy by remitting TK protection discussions to the WIPO. If developing countries

664 Horton, supra note 84 at 25.
666 Anderson, supra note 613 at 39.
667 Susy Frankel, “Attempts to Protect Indigenous Culture through Free Trade Agreements” in Christoph B Garber, Karolina Kuprecht & Jessica C Lai, eds, Int Trade Indig Cult Herit (Cheltenham, UK ; Northampton, MA, USA: Edward Elgar Publishing) at 134.
668 Ibid at 134–135.
succeed in including TK protection under the TRIPs regime, the framework of protection would benefit from the strong WTO dispute settlement mechanism.

To this effect, some scholars have suggested ways in which the TRIPs agreement could be made to accommodate TK protection. For instance Silke von Lewinsky points to Article 39 on ‘the protection of know-how’ as the most promising area for considering TK protection under TRIPs.670 Jane Anderson points to the protection of Geographical Indications as a feasible, though limited, route for deliberation on TK protection under TRIPs.671 However, the protection available under both proposals will be limited to the protection of TK meeting the strict requirements of patent laws such as novelty (newness) and inventive step (non-obviousness). As outlined in the section on IP and TK in Chapter One and discussed throughout this dissertation, most TK does not fulfill the core requirements of patent laws. Therefore, attempts to protect TK under TRIPs will require major reforms that would disrupt significantly the IP system.

Curtis Horton argues that a combined reading of Article 27 (1) and footnote 5 of the agreement may create a space that could be used for TK protection.672 Article 27 (1) states that “… patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” [Emphasis added] Footnote 5 is inserted to further note the alternative wordings of ‘novel’ and ‘non-obvious’ used in some jurisdictions instead of the phrase ‘newness’ and ‘inventive step’ respectively. Horton’s argument is that since the terms ‘inventive step’ and ‘non-obviousness’ are used as synonyms, the combined reading of Article 27 (1) and footnote 5 reveals that the TRIPs Agreement requires the provision of petty patent protection. Petty patents (otherwise called utility models) are exclusive rights granted for inventions that may not fulfil the inventive step/non-obviousness test. Horton claims that the minor improvements in TK development would be eligible to receive petty patent protection given the combined reading of articles 27 (1) and

670 Lewinski, supra note 227 at 37.
671 Anderson, supra note 613 at 39.
672 Horton, supra note 84 at 26–27.
This, however, does not seem to be the case. The intent of footnote 5 seems to be to ensure that there are no discrepancies in the use of the two terms ‘inventive step’ and ‘non-obviousness’ in different jurisdictions. The purpose of footnote 5 does not seem to be to broaden the scope of the term ‘patent’ to include petty patents. Horton himself seems to admit of this possibility in his writing.

In addition to scholarly attempts at interpreting the TRIPs agreement or reforming it, indigenous peoples and developing countries have been pushing for similar reform in diplomatic circles. For instance, a group of several indigenous peoples published the ‘Seattle Declaration’ at the 3rd WTO ministerial meeting in November, 1999 criticizing the TRIPs Agreement for, among other things, facilitating abuse of their knowledge and for failing to extend protection to TK. The declaration criticized the WTO for recognizing only ‘western’ knowledge systems and called on the organization to stop the unauthorized patenting of TK and explore alternative ways of protecting it. Despite these and many other attempts at interpreting the TRIPs agreement and calling for the inclusion of TK protection, the agreement as it stands does not provide TK protection.

Some member states of the WTO, mostly developing countries, have added their voices to the TK protection movement and pushed for the discussion of the issue in the TRIPs system. A key issue which has emerged from these discussions is the unresolved tension between the TRIPs agreement and the CBD. While the CBD recognizes that some sort of TK protection is needed for conservation purposes, the TRIPs agreement is silent on the matter. At the face of it, there does not seem to be any conflict. The tension arises from the concern that TK protection could

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675 See recommendation regarding TRIPs (3, c,d and f), *ibid.*
676 Quinn, *supra* note 615 at 300.
677 Most of the submissions made at the meetings of the Council for TRIPs were from developing countries and the Africa Group which tend to hold most of the world’s TK and genetic resources. For a list of submissions made by member countries, see the annex list B. Council for TRIPs, *The Protection of Traditional Knowledge and Folklore - Summary of Issues Raised and Points Made (IP/C/W/370/Rev.1)* (World Trade Organization, 2006).
lead to a violation of the intellectual property rights protected under the TRIPs agreement.\(^{679}\) It is not clear which instrument would trumps in case of such potential conflict. Beyond this particular tension, the general relationship between the two instruments continues to be unresolved. A more general form of this tension is seen in the WIPO IGC deliberations which discussed in section 4.1.3 below.

An important development regarding the relationship between the two instruments is the Doha ministerial meeting held in November, 2001. The Committee on Trade and Environment held the first discussions on TK protection within the WTO framework in the context of reviewing TRIPs Article 27 (3) (b), which provides for the patentability of some life forms, and the relationship between the WTO and the CBD.\(^{680}\) The declaration that emerged from the meeting (the Doha Declaration) called on the Council for TRIPs to “examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.”\(^{681}\) The Doha Declaration also mandated the Committee on Trade and Environment (CTE) to discuss the relationship between TRIPs and the CBD. Both the Council and the Committee took up the matter and served as forums for deliberation on TK protection, among other issues. Generally, member countries of the WTO, most of which are also members of the CBD, agree to the two key principles under the latter: the prior informed consent,\(^{682}\) and access and benefit sharing\(^{683}\) principles. The high frequency with which these principles are used

\(^{679}\) A frequently discussed instance in which such conflict between the CBD and TRIPS might occur – the disclosure of origin requirement – is discussed towards the end of this sub-section. See discussion on the ‘disclosure of origin’ requirement.

\(^{680}\) Lewinski, supra note 227 at 38.

\(^{681}\) See paragraph 19, Doha WTO Ministerial Declaration (WT/MIN(01)/DEC/1 (2001).

\(^{682}\) The WIPO provides the following explanation for the term Prior Informed Consent (PIC) which is at times referred to as Free and Prior Informed Consent (FPIC): “The purpose of the use of the adjective ‘free’ is to ensure that no coercion or manipulation is used in the course of negotiations, while inclusion of ‘prior’ acknowledges the importance of allowing time to indigenous [peoples] to fully review proposals respecting the time required for achieving consensus. It also anticipates the reality that decisions, especially those relating to major investments in development, are often taken in advance with indigenous peoples. The notion of ‘informed’ consent reflects the growing acceptance that environment and social impact assessment are a pre-requisite for any negotiation process and allow all parties to make balanced decisions.” See “Prior Informed Consent” in World Intellectual Property Organization, supra note 163.

\(^{683}\) Access and Benefit Sharing (ABS) is generally understood to mean access by users of genetic resources and traditional knowledge with the expectation of benefit sharing arising out of their utilization.
in international instruments arguably signals the fact that they may have achieved a status as a basic principle in international TK protection. However, members are in disagreement as to the means of attaining the objectives sought under such principles.684

There are diverse issues that may spark conflicts between the CBD and TRIPs when it comes to implementation. One core method of implementing the principles and objectives of the CBD is the requirement for patent applicants to disclose the origins of TK or genetic resources if the applicant has used these resources in developing the invention being considered for patent right. However, the necessity and efficacy of this ‘disclosure of origin’ requirement is a subject of vigorous debate among member countries.685 A common objection to the adoption of the requirement is that it may hinder innovation because the process of disclosing all the origins of knowledge used in the inventive process may prove to be too cumbersome and may make such process more costly.

Megadiverse countries such as Brazil and India call for the amendment of the TRIPs Agreement to include a mandatory ‘disclosure of origin’ requirement for member states.686 Most developed countries have not been keen on amending the TRIPs agreement. For instance, the US as the most influential member of the WTO, objects to the TRIPs council’s jurisdiction over TK protection.687 The US, rather than amendments to the TRIPs Agreement, prefers national legislative measures and allowing interested parties to enter into contractual relations on a case by case basis without

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684 See paragraph 18 and the following, Pascal Lamy, Issues Related to the Extention of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and those Related to the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (WT/GC/W/633 TN/C/W/61) (2011).

685 World Trade Organization, “Article 27.3b, Traditional Knowledge, Biodiversity”, online: TRIPs: Issues <https://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm> at 27; Lamy, supra note 59, Paragraph 18 and the following.

686 See generally, Council for TRIPs, Doha Work Program – Relationship Between the TRIPS Agreement and the Convention on Biological Diversity - Appropriate action to be taken/decided by the General Council on TRIPS & CBD - Communication from Brazil, China, Colombia, Cuba, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Paraguay, Peru, South Africa, Tanzania, Thailand, Venezuela, LDC Group and ACP Group (WT/GC/W/590, TN/C/W/49) (2008); See also ibid.

additional legal regulation\textsuperscript{688} and Japan suggests the deliberation of such issues at the WIPO instead of the TRIPs forum.\textsuperscript{689} There are outliers, however, as developed countries such as Norway\textsuperscript{690} and Switzerland\textsuperscript{691} have called for the establishment of the ‘disclosure of origin’ requirement within the TRIPs.\textsuperscript{692} Although the position of countries on the establishment of the ‘disclosure of origin’ requirement does not rigidly correlate to their level of economic development, the general division on positions does reflect a North-South divide. However, a limited disclosure of origin requirement, the violations of which does not have severe implications for patent holders, seems to enjoy popular support.\textsuperscript{693} Despite these vigorous deliberations in the past, the Doha round of deliberations on development issues including TK protection seems to have stalled.\textsuperscript{694}

To sum up the discussions on TK protection under TRIPs, even though the issue has been debated for well over a decade a concrete outcome has yet to be achieved. The debate is between megadiverse countries who call for TK protection through amendments to the TRIPs Agreement and some member countries (mostly developed countries) who object to such amendments and prefer either no amendments or less intrusive alternative measures. The current trend seems to be to discuss intellectual property issues related to TK protection under the WIPO framework. The

\begin{thebibliography}{9}
\bibitem{688} Council for TRIPs, \textit{Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore - Communication by the United States (IP/C/W/449)} (2005) at 3.
\bibitem{689} See generally, Council for TRIPs, \textit{The Patent System and Genetic Resources - Communication from Japan (IP/C/W/472)} (2006).
\bibitem{691} See generally, Council for TRIPs, \textit{The Relationship between the TRIPS Agreement, The Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore and the Review of Implementation of the TRIPS Agreement under Article 71.1 - Communication from Switzerland (IP/C/W/446)} (2005).
\bibitem{693} WTO Committee on Trade and Environment, “Environment: Issues - Intellectual property and the environment”, online: <https://www.wto.org/english/tratop_e/envir_e/trips_e.htm>.
\bibitem{694} Oguamanam, \textit{supra} note 669 at 322.
\end{thebibliography}
TRIPs agreement as it stands does not extend protection to TK. As a result, proponents of TK protection might have missed a key opportunity to benefit from the effective implementation and enforcement mechanism of the WTO.

### 3.4 Human Rights and Other Instruments

In contrast to the specific deliberations at the WTO, states have been more willing to include references to TK protection under human rights instruments. However, the common feature of these instruments is that they tend to be aspirational or general rather than providing rights and obligations that could be enforced. Many instruments have directly or indirectly called for TK protection. Several United Nations agencies and other international entities work on TK protection from the perspective of their core mandate. Most of these institutions collaborate on some aspect of their work with other entities working on TK protection. As stated earlier, because of TK’s relevance to biodiversity, biotechnology, food, agriculture and indigenous rights issues, many of the instruments that govern such issues internationally also touch on TK protection. Because of the diversity and high number of such initiatives a detailed analysis of the TK protection within these forums is beyond the scope of this chapter. However, a brief discussion of the work of the main international institutions and instruments which have implications for TK protection is provided below.

The Food and Agricultural Organization (FAO) is a key forum in which genetic resources and traditional agricultural knowledge have been discussed. The FAO administers the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA) which was adopted at the organization’s 31st session in November, 2001. The main success of the treaty is in establishing an innovative Multilateral System of Access and Benefit Sharing. The Multilateral

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695 For a list of the various UN agencies and projects on TK protection, see United Nations University - Institute for the Advanced Study of Sustainability, “Traditional Knowledge & the UN”, online: <http://www.unutki.org/default.php?doc_id=23>.

696 The International Treaty on Plant Genetic Resources for Food and Agriculture, UNFAO, 3 November 2001 [The International Treaty on Plant Genetic Resources for Food and Agriculture].

697 See Part IV, Article 10 and the following, *ibid.*
System is a common pool framework that covers 64 of the most important crops for humankind (representing 80% of human consumption). The system allows citizens of signatory countries to use the resources provided on the condition that they use them for non-commercial purpose and not to acquire IP rights over such resources (see Article 12.3). The treaty also requires diverse forms of benefit sharing if the resource is used for commercial purposes (see Article 13.2). It should be noted here that the IT PGRFA is designed to complement the CBD’s core principles of access and benefit sharing and it has built on the CBD by recognizing farmers’ rights to participate in decision making (Article 9 (2,c) and to share benefits (Article 9 (2) and 13).

Most areas of TK seem to be covered when one combines the CBD, which calls for the protection of TK associated with biodiversity conservation, and IT PGRFA which calls for the protection of TK “relevant for genetic resources for food and agriculture.” However, the IT PGRFA, similar to the CBD, has highly qualified language and frequently defers to national legislation. As such, the progress on TK protection through these instruments is limited.

A more relevant UN agency for the purposes of traditional medicinal knowledge is the World Health Organization (WHO). Established in 1948 as a specialized and independent agency of the UN, the WHO’s work focuses on issues of global public health. It is in this context that the WHO approaches TMK and intellectual property issues. In December 2000, the organization discussed the issue at an Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. Member states made 11 core recommendations, the most important of which include the protection of TK (including through customary and sui generis means), the documentation of public domain traditional knowledge, the establishment and strengthening of national and regional approaches, and the creation of benefit sharing schemes.

A year later the WHO published its first Traditional Medicine Strategy for the period 2002-2005 which focused on learning from the opportunities and obstacles to using traditional medicine in

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698 See Annex 1 of *ibid*.
699 Note 145.
700 See chapter 9 on page 34-35 *ibid*.
Building on this document, the WHO recently published a follow-up strategy for the period 2014 – 2023. The focus of these initiatives is the support of domestic policies and strategies for traditional medicine in general. As such, the intellectual property protection of TMK is only a small part of the strategy. However, the extensive work of the WHO on the subject of traditional medicine validates this body of knowledge and practice in international and domestic forums. The organization has passed several resolutions highlighting the importance of traditional medicine around the world, especially in developing countries.

In addition to the above agencies, other specialized UN entities have discussed TK protection in one form or another. These can generally be grouped into agencies with a human rights and cultural focus, trade and development agencies, and those working on environmental protection. The first group includes the Economic and Social Council (ECOSOC), the United Nations High Commissioner for Human Rights (UNHCHR), and the United Nations Educational, Scientific, and Cultural Organization (UNESCO). A brief discussion of the work of these institutions follows.

The ECOSOC has worked on TK protection through a number of initiatives. Its work on TK was carried out through two sub-institutions, the Working Group on Indigenous Populations and the Permanent Forum on Indigenous Issues. A key result of these deliberations is the Declaration on the Rights of Indigenous Peoples adopted in 2007. Article 31 of the declaration is important as it recognizes the right of indigenous people to “maintain, control, protect and develop their … traditional knowledge … as well as the manifestations of their sciences, technologies … medicines, knowledge of the properties of fauna and flora…” Although the article is found in a UN General Assembly declaration which is non-binding, it “articulates the contemporary

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703 UNCTAD, supra note 616 at 7.
705 Article 31, ibid.
international consensus on TK protection. The provision may, if the requirements of ‘state practice’ and ‘opinion juris’ are met, form part of customary international law.

The Principles and Guidelines on the Protection of the Heritage of Indigenous Peoples of the UNHCHR was one of the first attempts at establishing human rights standards for TK protection. The instrument defined heritage broadly to include traditional knowledge, literary and artistic expressions and artifacts. Despite several revisions, the Principles and Guidelines were not adopted and they have not resulted in an enforceable instrument. While recognizing the value of the Principles and Guidelines in promoting the global TK protection movement, they have failed to provide a satisfactory mechanism that would benefit knowledge holder communities.

The UNESCO has dealt with TK protection in a number of ways. It works to implement the Universal Declaration on Cultural Diversity which states the need for protecting traditional knowledge. The Convention for the Safeguarding of the Intangible Cultural Heritage also falls under the UNESCO framework and the term protected ‘intangible cultural heritage’ includes TK

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706 Oguamanam, supra note 606 at 154.
707 In principle, United Nations resolutions or declarations are non-binding under international law. See Legality of the Threat or Use of Nuclear Weapons Case, Advisory Opinion (International Court of Justice), [1996] ICJ Report 226, 254 - 255. However, if the customary international law requirements of “state practice” and “opinio juris” are met, it is possible that such declarations could form part of binding customary international law. ; The United Nations Permanent Forum on Indigenous Issues explains: “UN Declarations are generally not legally binding; however, they represent the dynamic development of international legal norms and reflect the commitment of states to move in certain directions, abiding by certain principles. The Declaration UNDRIP, however, is not widely interpreted as creating new rights. Rather, it provides a description of human rights enshrined in other international human rights instruments of universal resonance as these apply to indigenous peoples and indigenous individuals. It is in this sense that the Declaration has a binding effect for the promotion, respect and fulfillment of the rights of indigenous peoples worldwide...”United Nations Permanent Forum on Indigenous Issues, Declaration on the Right of Indigenous Peoples: Frequently Asked Questions.
710 Quinn, supra note 615 at 309.
711 See Annex II, action plan of UNESCO, objective 14 Universal Declaration on Cultural Diversity, UNESCO, 2 November 2001 [Universal Declaration on Cultural Diversity].
in the sense used in this dissertation. The UNESCO partnered with the International Traditional Knowledge Institute to establish an open user-generated repository of traditional knowledge named the Traditional Knowledge World Bank. The organization is also responsible for the creation of the Local and Indigenous Knowledge Systems in a Global Society (LINKS) project which, among other things, seeks to examine and strengthen customary rules regarding the management of traditional knowledge.

The work of the human rights-focused UN institutions is complemented by the agencies whose core mandate relate to global trade and development. The United Nations Conference on Trade and Development (UNCTAD) and the United Nations Development Program (UNDP) have examined the relationships between TK protection, global trade, and development. UNCTAD is given the broad mandate to work on issues at the intersection of global trade and development. In the year 2000, UNCTAD hosted an Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations, and Practices which was attended by leading experts from diverse fields who deliberated on policy options for TK protection. The organization followed up on this initial work with other seminars and a joint workshop with the Commonwealth Secretariat in 2004. Given the broad mandate of UNCTAD and the participation of other key international organizations in these meetings, it seems that these deliberations have helped move discussions in other forums. The UNDP for its part has taken the approach of mainstreaming indigenous people’s perspectives in all sectors of the program. This includes environmental protection and human development. Along the lines proposed in this

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715 UNCTAD, supra note 616.

716 Lewinski, supra note 227 at 44.


718 UNCTAD, supra note 616 at 9.
dissertation, the UNDP created the Indigenous Knowledge Program in collaboration with the Indigenous People’s Biodiversity Network with the goal of documenting and conserving TK.\textsuperscript{719}

Although not a key player in such discussions, the World Bank has also reacted to the international movement to protect TK. Following its core mandate, it has approached the issue from a global development perspective. It has collaborated with several entities, including the WIPO and the WHO to create the Indigenous Knowledge Initiative with the objective of establishing a global TK database.\textsuperscript{720} The initiative was pursued under the Partnership for Information and Communication Technology for Africa (PICTA) project and it promoted the use and exchange of TK.\textsuperscript{721} Adopting a more holistic approach the World Bank also re-evaluated its policies and procedures to ensure that they become more responsive to the needs and expectations of indigenous peoples.\textsuperscript{722}

As can be deduced from this section, the interests and expectations of the various stakeholders involved in TK protection are highly diverse. TK protection is a cross-cutting issue that has implications for environmental protection and biodiversity conservation, socio-cultural and economic development, health and agriculture. As stated above, this has resulted in the issue being discussed in many international forums where each has a particular area of focus. Such an approach, where each forum brings to bear its own expertise, may offer considerable advantages, especially when these forums collaborate with each other to avoid overlap. However, without a lead institution with clear authority, there is risk of a piecemeal approach to TK protection that fails to yield a comprehensive solution to the problems.\textsuperscript{723}

While input from these diverse specialized international entities is indispensable, there is a need to establish a lead organization that takes a holistic approach to deliberations on TK protection.

\textsuperscript{719} Ibid.
\textsuperscript{720} World Bank, \textit{Indigenous Knowledge for Development (Brochure)}.
\textsuperscript{721} UNCTAD, \textit{supra} note 616 at 9.
\textsuperscript{722} Ibid.
\textsuperscript{723} Twarog, \textit{supra} note 717 at 61.
Such an approach will be more effective in moving deliberations on TK protection forward. As will be discussed below, the WIPO seems to be assuming a lead role. The negotiations taking place at the WIPO-IGC focus on TK protection in an independent and holistic manner rather than focusing on any particular aspect of it. Tellingly, it is also the most advanced debate on TK protection. Many states hope the draft articles being negotiated at the WIPO-IGC will result in an effective global mechanism that provides clear solutions unlike previous attempts at TK protection. The following section is devoted to examining the key features of the draft articles instrument on TK protection from the perspective of the core thesis of this dissertation – the need to establish a framework that encourages the codification and disclosure of such valuable bodies of knowledge.

4 The WIPO Draft Articles and the ‘Incentive to Codify’

The ‘Protection of Traditional Knowledge: Draft Articles’\textsuperscript{724} - an instrument that WIPO IGC has been working on for a decade - is a highly contentious instrument. The contentions relate to both the general nature and purpose of the document and the details of almost all twelve provisions within it.\textsuperscript{725} The nature of the document will substantially change depending on which alternative wording or option is ultimately accepted under each provision.\textsuperscript{726} Because of the tentative nature of most of the provisions, detailed analysis of the rights and obligations proposed in it is infeasible. Instead, what is provided below is a general discussion of key features of the instrument that create fault lines in the deliberations at the WIPO IGC. Such discussions will focus on how these issues affect the codification and disclosure of traditional medicinal knowledge as developed in earlier chapters.

\textsuperscript{724} World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, \textit{The Protection of Traditional Knowledge: Draft Articles} (WIPO, 2013) [Draft Articles] The latest version at the time of the writing of this chapter was published on March 28, 2014 and thus the analysis discussed in this chapter will be based on such version.

\textsuperscript{725} See Annex 1 to the dissertation

\textsuperscript{726} For a more detailed discussion of the key elements of an earlier version of the Draft Articles see, Tobias Kiene, \textit{The Legal Protection of Traditional Knowledge in the Pharmaceutical Field: An Intercultural Problem on the International Agenda} (Münster; New York, NY; München; Berlin: Waxmann Verlag GmbH, Germany, 2011).
The Draft Articles have three parts: The preamble/introduction, the policy objective, and the substantive and procedural provisions. A brief discussion of each section is provided below. An analysis of the key features that seem to create an unbridged gap will follow thereafter.

The preamble/introduction has nine distinct but interrelated statements on TK protection listing the goals of the Draft Articles. The section includes paragraphs on the recognition of the value of TK, the need to promote awareness of and respect for TK, the promotion of preservation of TK, the relationship between the Draft Articles and other international agreements and processes, the promotion of access to knowledge and safeguarding of the public domain, the documentation and conservation of TK, the promotion of innovation, the creation of new rules and principles, and the relationship of the framework with customary use. Paragraph six of this section is particularly important for the purposes of this dissertation because it highlights the need for the documentation, conservation, and disclosure of TK. The paragraph states:

Document and conserve traditional knowledge

(vi) contribute to the documentation and conservation of traditional knowledge, encouraging traditional knowledge to be disclosed, learned and used in accordance with relevant customary practices, norms, laws, and/or understandings of traditional knowledge holders, including those customary practices, norms, laws and/or understandings that require prior informed consent or approval and involvement and mutually agreed terms before the traditional knowledge can be disclosed, learned or used by others;[Emphasis added]

Given that this is the only paragraph which does not have brackets, it seems that all members of the WIPO IGC agree with the need to document, conserve and disclose TK. It should be noted

[727] See the Preamble/Introduction section, Draft Articles, supra note 723.

[728] Paragraph six of Preamble/Introduction, ibid.
that the paragraph recognizes the basic standards of ‘prior informed consent,’ ‘approval and involvement,’ and ‘mutually agreed terms.’ Although these principles are being debated with regard to their specific application, their inclusion in many of the international instruments dealing with TK suggest that they have achieved a certain stature as accepted principles in the international deliberation of TK protection. It should be noted here that the documentation of TK is a new addition as a core goal of the Draft Articles. Previous versions of the Draft Articles do not mention the need to document or codify TK. As such, it could be thought of as a new consensus for advancing the goal of international TK protection.

The title of this first part – preamble/introduction – seems to be where we see our first sign of contention in the instrument. Since preambles are customary sections in documents of a strong legal nature it seems that some members of the committee prefer to use the term ‘introduction’ which implies that the document has little legal force behind it. The contention does not stop with the title. Complete wording of three of the nine preambular/introductory statements is contested. The paragraphs on the promotion of access to knowledge and the safeguarding of the public domain, and those on the provision of new rules and disciplines have been put in brackets to show that some prefer to delete the entire statement deleted from the instrument. Some members have provided an alternative paragraph to the statement on the promotion of awareness and respect for TK.

Additionally, key features of almost all paragraphs in this preambular/introductory section are also put in brackets because of disagreements on wordings. For instance, the first paragraph focusing on the recognition of the value of TK lists the several values that TK might have for society including intellectual, spiritual and social values. However, it seems that members could not agree on the recognition of the economic/commercial values of TK as these terms have been put in brackets.

In contrast to the nine statements under the preamble/introduction, the policy objectives focus on two main issues: the granting of certain rights to knowledge holding communities and the prevention of the granting of erroneous patent rights over TK. Despite their focus on these two issues, the statements in the policy objectives section are also filled with alternative statements.
The above section has briefly discussed the first two sections of the Draft Articles: the preamble/introduction and the policy objectives. The following section will discuss the key issues that have created gaps between the negotiating positions of member countries, which in some instances have resulted in the creation of groupings of like-minded states. As stated above, while a detailed discussion of each article in the instrument is not feasible, an examination of the core issues that have stalled the Draft Articles deliberation seems useful at this point. It is hoped that such discussion will shed some light on the contents of the third section of the Draft Articles – the substantive and procedural provisions.

4.1 Key Issues of Contention

The key issues that have given rise to tension between the negotiating blocks may generally be grouped into four topics. These include: 1) the definition of TK, especially on whether it should be expanded to include traditional cultural expression or limited to traditional knowledge; 2) the legal nature of the Draft Articles (i.e. whether they should be a binding international instrument or some version of a soft law or guideline); 3) the recurring tension between inserting flexibilities in the instrument and attempting to make it effective and enforceable; and 4) the interaction between TK systems of protection and existing intellectual property laws; that is which should prevail in case of irreconcilable conflict. These core issues, discussed in further detail below, have divided member countries of the WIPO IGC ever since details of the instrument began being discussed in this forum. While these issues have implications for many areas of the Draft Article and TK protection, the analysis in this section focuses mainly on the effect of the issues on the encouragement of TK codification and the effectiveness of the bioprospecting right proposed in previous chapters.

A rough grouping of the member countries on all sides of the debate shows divisions along levels of economic development. As discussed in earlier chapters, developing countries which hold most TK generally tend to advocate stronger protection of TK while developed countries, in which most multinational corporations that use TK reside tend to resist strong protection of TK. This can be seen in the deliberations of the IGC and the positions that member countries take. However, there are some outlier developed countries that defy such categorizations by taking a mid-way
position. New Zealand, Australia, Norway and Switzerland seem to be members that tend to take such positions on some occasions. Additionally, as explained earlier in Section 3.2, the divide in the IGC debate is more complex than just a simple grouping of countries divided based on their level of economic development. It involves like-minded countries which have diverse interests within a broader agenda, and positions which are adopted as part of a broad political strategy that spans issues and international forums of deliberation.

4.1.1 Tensions in Defining TK

Most indigenous peoples and local communities see TK as an integral part of their culture and identity. Representatives of indigenous groups who have attended the WIPO IGC process have noted this fact on several occasions. Their call is for TK protection to be discussed together with traditional cultural expressions and genetic resources. WIPO also recognizes the interconnectedness of these issues and these issues were dealt with together at the beginning of the IGC process. However, as deliberations progressed at the IGC, the committee began dealing with TK separate from traditional cultural expressions and genetic resources, while still recognizing their interconnected and holistic nature. Currently, there are separate workshops, negotiations, and instruments for TK, traditional cultural expressions, and genetic resources.

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729 For instance, see comments made by delegations from New Zealand, Australia, Norway and Switzerland. Circulation of Comments Received on Documents WIPO/GRTKF/IC/9/4 AND WIPO/GRTKF/IC/9/4 (WIPO/GRTKF/IC/10/INF/2) (World Intellectual Property Office, 2006); The Protection of Traditional Knowledge: Addendum to Collation of Written Comments on the List of Issues (WIPO/GRTKF/IC/11/5(a) Add.) (World Intellectual Property Office, 2007) at 3 Annex. As highlighted earlier Norway and Switzerland have been leaders in the amendment of the Patent Cooperation Treaty and the International Patent Classification to include TK.


731 Kiene, supra note 726 at 215.


The Draft Articles document reflects this tension in defining TK. The ‘use of terms’ section of the Draft Articles, which provides definitions for key legal terms used in the instrument, adopts the following definition of TK:

*Traditional knowledge* [refers to]/[includes]/[means], for the purposes of this instrument, know-how, skills, innovations, practices, teachings and learnings of [indigenous peoples] and [local communities]/[or a state or states].

[Traditional knowledge may be associated, in particular, with fields such as agriculture, the environment, healthcare and indigenous and traditional medical knowledge, biodiversity, traditional lifestyles and natural resources and genetic resources, and know-how of traditional architecture and construction technologies.]

The first paragraph of this definition adopts a narrow scope and limits the definition to what is defined in this dissertation as TK. The second paragraph situates TK in a holistic manner as a concept interconnected with “traditional lifestyles” and “genetic resources”. However, the second paragraph is fully placed in brackets which means member countries did not all agree that the second paragraph should be part of the definition of TK. The link between TK and cultural expressions is also mentioned in Article 1 (b) of the Draft Articles. In outlining the subject matter of protection the Draft Articles acknowledge that TK is somehow linked to “the cultural[and/[or] social identity and cultural heritage of indigenous peoples] and local communities …”" While these disagreements may seem to be minor technicalities, the debate about the scope of TK has been one of the key issues stalling the deliberation of the Draft Articles.

The tension over defining TK is related to the underlying differences in the world view of ‘modern societies,’ on the one hand, and indigenous peoples and local communities on the other. The tendency to divide TK from traditional cultural expressions seems to stem from two factors - existing practice and pragmatism. The preference for following existing practices in conventional

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734 Draft Articles, *supra* note 723 Article 1 (b).
intellectual property literature and legislation may be the first root cause. While traditional know-
how relates to the subject matters of protection under patent law, traditional cultural expressions
are more closely associated with literary and artistic expressions protected under copyright law.
Consequently, members of the IGC may have chosen to be pragmatic and simply cluster the issues
into a ‘western’ categorization of intellectual properties.\(^{735}\)

Following the pragmatic route, the definition adopted in this dissertation is a narrow one and
refers to the know-how, skills, practices and innovations of indigenous peoples and local
communities. However, as discussed in the previous chapter, TMK codification should be as
holistic as possible. Holistic documentation of TK covering the cultural context in which it was
developed is more valuable to the biopharmaceutical industry as it may provide more informative
ways of developing successful drugs. In addition to this utilitarian function, holistic
documentation may serve to satisfy interests other than those specific to bioprospecting. This may
include historical and anthropological values that holistic documentation may protect. This is not
to argue that the bioprospecting right should extend to the expressive elements of the codification.
Even if TMK is documented in a holistic manner within its cultural context, the features that
would give rise to bioprospecting rights and responsibilities would be limited to the medicinal
know-how that is used in bioprospecting projects. Therefore, while a narrow definition that refers
to know-how, rather than cultural expressions, is preferred in this thesis, the actual codification
does not need to exclude the cultural context in which TK is found.

4.1.2 The legal nature of the Draft Articles

The most contentious issue at the IGC seems to be the legal nature of the Draft Articles.\(^{736}\)
Member countries have been consistently divided on the question of whether the process should
focus on establishing a legally binding international instrument or a non-binding document. The
implication of this disagreement seems to be the major issue stalling the progress of deliberations
at the IGC. The interests of member states with regard to what form the Draft Articles should take
are widely diverse. For example, the United States has consistently voiced its objection to the

\(^{735}\) Kiene, *supra* note 726 at 240.
\(^{736}\) *Ibid* at 234–235.
establishment of a binding legal instrument preferring to leave the instrument as a suggestive
document, while the European Union has preferred to leave the option open for future decision
making. The delegations of Australia and New Zealand have proposed the adoption of
guidelines that the latter calls a “menu of options approach.” Developing countries such as
India, Turkey, and Brazil, among others, and the African Group argue that TK protection will not
be effective without a binding international instrument. Because member countries have yet to
agree on what legal form the Draft Articles should take, the most recent version of the instrument
does not reflect much progress since its earlier versions.

As discussed in the earlier sections of this chapter, several international instruments adopt general
statements on the need to protect TK. The problem is not a lack of international documents
providing aspirational statements and general principles. Rather, the lack of a clear and binding
legal instrument seems to be what is missing. The gap in the positions of states and the resulting
frustration with the lack of progress may be one of the causes of the protectionist trend that
megadiverse countries are adopting. Thus, although limited in scope, some form of binding
international instrument will be necessary if the global use of TMK in bioprospecting projects is
to achieve its full potential. The preambular/introductory statements and policy objectives are
general areas where there is considerable consensus. Therefore, some form of minimum
protection could be developed out of such provisions. Therefore, what is needed is a point of
maximum consensus that would garner the support of key jurisdictions in the global
bioprospecting field and still be able to provide enough protection to facilitate the codification
and disclosure of TMK.

As mentioned earlier, the need to document and conserve TK is one of the few uncontested
preambular/introductory statements in the Draft Articles. As such, the need to incentivize the
codification of TK could be used as an organizing principle for establishing minimum binding

737 See generally statements made by the EU and USA The Protection of Traditional Knowledge: Factual
Extraction (WIPO/GRTKF/IC/12/5(b)) (World Intellectual Property Office) at 8–10.
738 Kiene, supra note 725 at 235 It seems that the existence of a considerable and vocal indigenous peoples in
Australia and New Zealand has succeeded in influencing the position of these governments at the IGC.
739 See generally comments made by India, Brazil and the African Group note 737 at 84.
protection. The binding nature of TK protection could have significant implications for its effectiveness which, in turn, may be expected to impact the framework’s ability to create a sustainable system of codification and disclosure.

4.1.3 Flexibilities Vs Effectiveness/Enforceability

The other major point of contention evident in many documents of the IGC negotiations is the tension between flexibility and effectiveness. On the one hand, groups made up of developing states and indigenous peoples, and local communities are pushing for the establishment of some sort of clear and enforceable legal documents while, on the other hand, a group of developed countries advocates the need to preserve flexibilities. The call for flexibilities includes arguments for the need to leave policy space for member countries to establish TK protection systems that respond to the unique features of their jurisdictions, national interests, and the socio-political climate. Actors calling for flexibilities also point to the scope of protected TK as an area requiring flexibility.

A close observer of the politics of international IP law\textsuperscript{740} may find some irony in such statements as most of the countries that push for the establishment of flexibilities in international TK protection system are the same actors who lead international efforts for the harmonization of stronger international IP laws. For instance, the United States is a leader in the international harmonization of intellectual property laws through both multilateral and bilateral agreements. However, the US delegation at the WIPO IGC has consistently focused on respect for “the important concepts of freedom of choice and flexibility for Member States addressing these issues and concerns.”\textsuperscript{741} Similarly, the Canadian delegation commented that IGC’s work “would have to allow for maximum flexibility to take into account the diverse nature of Committee members’

\textsuperscript{740} It should be noted that there is no single and organized body of ‘international intellectual property law.’ The term ‘international intellectual property law’ is used loosely and for the sake of convenience to refer to the body of laws that have direct implications for the regulation of the creation, use and distribution of inventions, and literary and artistic creations.

\textsuperscript{741} Draft Report (Second Draft) WIPO/GRTKF/IC/9/14 Prov 2. (Secretariat of the World Intellectual Property Office, 2016), para 204.
present and future efforts …”\textsuperscript{742} This can be contrasted to the position of these countries on other international treaties in which international obligations limiting domestic policy space are accepted with much more enthusiasm.

This is not to say that calls for flexibilities are illegitimate. There is a genuine need to provide policy space for member countries to establish an appropriate TK protection system for their own jurisdictions based on their socio-political and economic realities. Given the diversity of stakeholders involved in the conservation and use of TK, and the different interests in this regard, it may be impossible or at least premature to establish a globally harmonized TK protection system. However, as is done in other areas of international law in general and international IP instruments in particular, the goal should be to balance flexibility with legal certainty and enforceability. In this sense, some level of protection that reflects the minimum consensus at the international level seems justifiable. This is especially necessary given the failure of general and vague statements in existing international instruments to address the problem of TK loss and ensure its sustained use.

As repeatedly highlighted in previous sections of this dissertation, the focus should be on addressing the common problem of the alarming rate of TK loss and the inefficiencies associated with using TK. In this regard, there is general agreement on the need to halt the ‘misappropriation’ of TK and to limit the granting of non-innovative patents.\textsuperscript{743} A balance should be struck between providing flexibility for member countries to establish differing domestic laws and the provision of some baseline protection ensuring legal certainty and enforceability. As highlighted in previous chapters, the uncertainty related to TK protection creates major transaction costs that discourage users from using TMK in bioprospecting projects.\textsuperscript{744} If an international legal regime could

\textsuperscript{742} Ibid, para 224.

\textsuperscript{743} Compilation of Comments Received On the Second Draft of an Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications Subsequent to an Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements (WIPO/IP/GR/05/INF/5) (World Intellectual Property Office, 2005) at 13 Annex.

\textsuperscript{744} Kiene, supra note 726 at 242; Carvalho, supra note 3 at 246.
provide some level of certainty and consistency, the incentivizing effect of legal intervention for the codification and disclosure of TMK could be expected to increase.

4.1.4 The Interactions between TK protection and existing IP Law

The relationship between the Draft Articles and existing international instruments, including IP laws, has been another issue upon which members of the IGC have not agreed. While some members of the IGC, including the European Union, push to make the Draft Articles consistent with existing international IP laws, other members, (mostly developing countries such as Brazil and India) and the African Group, argue that this would unfairly subordinate TK protection systems to existing systems of IP protection.\textsuperscript{745} The Indian delegation has noted that “the genesis of the [IGC] could be traced back to the shared understanding that the IP system should be supportive of the protection of TK and not run contrary to its objectives and principles.”\textsuperscript{746} The Brazilian delegation has added that existing IP rules are part of the problem as acts of bio-piracy use weaknesses in existing patent laws to misappropriate TK.\textsuperscript{747} This gap in views has persisted to date and can be seen in the Draft Articles.

The fourth preambular/introductory provision in the most recent version of the Draft Articles states that the instrument should “take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that relate to intellectual property and access to and benefit sharing of genetic resources which are associated with that traditional knowledge.”\textsuperscript{748} This paragraph is one of the two uncontested preambular/introductory statements. If the instrument is approved with such wording the proposed system of TK protection may have to comply with existing IP laws inclusive of features that may undercut its core purpose. On the face of it, the last part of the provision calling for consistency with existing systems of “access to and benefit sharing of genetic resources” may seem to have

\textsuperscript{745} Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Seventh Session - Report (WIPO/GRTKF/IC/7/15) (Secretariat of the World Intellectual Property Office, 2005), paras 11, 15, 110, 120, 126.
\textsuperscript{746} Ibid, para 106.
\textsuperscript{747} Ibid, para 110.
\textsuperscript{748} See Preamble/Introduction, paragraph 4, Draft Articles, supra note 723.
some potential to save the Draft Articles from becoming subordinate to existing IP laws. This is so because the phrase ‘access and benefit sharing’ mechanism seems to be a reference to the system established under the Convention on Biodiversity. However, as discussed in earlier sections of this chapter, the CBD framework is limited in its ability to protect TK since the wording adopted in the framework is highly general and mostly aspirational. As a result, the preambular/introductory statement calling for consistency with existing laws will mainly refer to the strong IP rights that fail to protect TK. Consequently, this might further limit the potential of the Draft Articles to bring about effective TK protection framework by making them subordinate to existing laws.

The more substantive provision on the matter, Article 10 states: “[t]his instrument [should]/[shall] establish a mutually supportive relationship [between intellectual property [patent] rights [directly based on] [involving] [the utilization of] traditional knowledge and with relevant [existing] international agreements and treaties.”749 [Emphasis mine] The term ‘mutually supportive’ is unclear. It does not seem to make the Draft Articles subordinate to other instruments, but it also does not state that the instrument should trump other instruments in cases of conflict. In an international arena where most other relevant instruments, including the TRIPs Agreement, prohibit signatories from agreeing to conflicting obligations in other instruments, the neutrality of the Draft Articles may ultimately result in their subordination to other instruments.

The relationship of the Draft Articles to other instruments may affect the incentive of knowledge holding communities to codify and disclose their TMK. This is because existing IP laws could be used against the interest of knowledge holding communities. For instance, there is no binding international patent instrument requiring the disclosure of TK used in the process of an invention. Users may obtain a patent on an invention that was based on TK. Thus, knowledge holder communities may hesitate to codify and disclose their knowledge if documentation means easy access to outsiders who may receive exclusive rights over such knowledge.

749 Proposed Article 10, ibid.
To summarize the points made in this section, the Draft Articles are replete with contentious alternative wordings that make detailed analysis of the provisions contained in it infeasible at this time. The nature of the Draft Articles will change drastically depending upon which wordings are accepted in its final version. Instead of a detailed analysis of the instrument, the above section has examined the key issues of contention followed by an investigation of the implications for the codification and disclosure of TK. The section has argued that a legally binding international instrument with a considerable level of certainty is needed in order to encourage the codification and disclosure of TK. Such an instrument will be capable of building confidence among knowledge holder communities that they will have a say in what happens to their knowledge once it is codified and disclosed.

The core argument in this dissertation revolves around the need to encourage the codification and disclosure of TMK through the granting of a ‘bioprospecting right.’ Now that the Draft Articles and their implications for codification and disclosure of TK have been analyzed, the following section will proceed to use the ‘incentive to codify’ as an organizing principle (a minimum consensus) to investigate the concepts and approaches that need to be adopted to provide sufficient international protection for TK. The section will also comment on attempts by developing countries to establish TK protection through Free Trade Agreements (FTAs).

5 Trends and Scenarios: A Minimum International Consensus

The above sections have shown the diverse levels of interests in protecting TK and the varied methods that stakeholders have adopted to achieve such goal. Thus, the purpose of this section is to examine what concepts could garner sufficient level of consensus needed to provide an effective protection of TK that would encourage its codification and disclosure. As such, the discussion will focus on a few of the many innovative approaches and tools proposed by scholars.

This chapter began by addressing the problem of extra-territorial free-riding that may arise from the territoriality of the proposed ‘bioprospecting right.’ The risk identified was that some countries which are net importers of TK might decline to establish any kind of TK protection system
domestically in order to make use of TK disclosed as a result of protection provided in another jurisdiction. While there may be domestic measures, such as confidentiality and deferred disclosure, which can increase the effectiveness of the proposed system, the full potential of the proposed framework will only be realized if there is some form of international framework that can facilitate the use of TMK in bioprospecting projects. The sub-sections below analyze some of the approaches that states might take at the international level to establish an effective framework.

5.1 Minimum Substantive Protection

As the key issues of contention at the WIPO IGC discussed in the previous section have shown, a major fault line in the deliberations is the question of which issues to address through international mechanisms and which to leave for domestic legal systems. The significant gap between the positions of groups of member states implies that the IGC process is far from creating a substantive international treaty. The potential solution seems to lie in an approach balanced between providing sufficient flexibilities to national legal systems to define what form TK protection will take within their jurisdictions and reducing the negative effects of the territoriality of such systems.

Consequently, the core question to respond to in terms of international protection would be, what sort of international protection could garner sufficient support among countries while also encouraging the documentation and disclosure of TMK? In order to respond to this question, one may need to look to the development of a similar legal framework under international law – patent laws. The history of international patent law goes back more than a century and begins with the signing of the Paris Convention for the Protection of Industrial Property [the Paris Convention] in 1883.750

Until the enactment of the TRIPs agreement under the framework of the GATT, international IP law provided substantial flexibilities for domestic legal systems to enact domestic IP laws that

750 Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979), 20 March 1883 [Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979)].
would meet international standards. The Paris Convention focused on two core elements: 1) the establishment of substantive minima – minimum features of domestic legislations that member countries were required to enact, and 2) a requirement to provide the same type of protection to citizens and foreign national – national treatment. The detailed definition and scope of protection were left to the domestic legal systems of member countries. Under such a system, signatories were prohibited from discriminating against foreign rights holders based on their nationality. However, they were required to provide IP protection to foreigners only if they provide the same rights to their citizens.

The TRIPs Agreement shifted this century old practice. Article 1 (3) of the TRIPs Agreement states that “Members shall accord the treatment provided for in this Agreement to the nationals of other Members.” Thus, signatories are required to provide protection to nationals of other countries even if the member country did not provide such protection under its domestic law. This is a drastic change to the international IP law framework. It is seen as the first major step towards the harmonization of IP laws at the international level. Additionally, the TRIPs Agreement also requires compliance with most favored nation treatment (MFN). The MFN principle requires member states to give the same treatment it provides to nationals of its ‘most favored nation’ to all members of the WTO. In the current international IP system, the requirements of national treatment and most favored nation treatment have been accepted as basic principles.

Given this brief history of the evolution of international IP law, the development of international TK protection should also begin with basic principles on which most member states have reached consensus instead of attempting to establish a globally harmonized substantive level of protection.

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752 TRIPs, supra note 60.
754 TRIPs, supra note 60 Article 4.
755 Reichman, supra note 753 at 347.
The TRIPs Agreement came about through intense pressure from developed countries including, most notably, the United States. An international TK framework has not garnered the same type of support from influential states. In fact, as discussed extensively in previous sections, most developed countries are opposed to a binding substantive international treaty on TK. Current advocates of international TK protection may not be able to influence international fora without the support of more developed countries. Thus, the most feasible path forward for the TK protection seems to be to begin from the minimum international consensus and to garner sufficient support from like-minded jurisdictions.

Since the basic principles of the national treatment and most favored nation treatment have become ubiquitous in international IP law, the use of such principles seems the logical starting point for the creation of an international TK protection framework. In fact, Article 11 of the Draft Articles requires national treatment. Surprisingly, Article 11 is also highly contested, with three different versions of the provision proposed. While two of the alternate provisions correspond to the basic principle of national treatment, the other is a clear statement allowing member states to provide “more extensive protection for their nationals” than to nationals of other member countries. It is not evident from the Draft Articles document how many countries are against the basic principle of national treatment. Therefore, it might be the case that most members agree to national treatment, but a few states objected to it, giving rise to a separate version. Despite the fact that the national treatment provision in the Draft Articles is contested, it seems to be one of the few provisions with the potential to be accepted by most member countries.

Given the two versions of national treatments available under international IP law, states will have to choose which one to insert in the proposed international instrument. Carvalho argues that a Paris Convention type of national treatment – one that requires countries to provide protection to foreign nationals only if they have domestic protection of TK – should be adopted rather than a TRIPs Agreement type of national treatment which requires some level of TK protection to foreigners even if a country has not enacted domestic laws to that effect. He posits that the Paris Convention type of national treatment “would give members with different views on the

\[\text{\textsuperscript{756} Carvalho, supra note 3 at 264–265.}\]
urgency and criteria for protecting TK at the national level the possibility of coming together and joining a single treaty and yet preserving a certain level of flexibility.™

On the face of it, the Paris Convention type of national treatment standard seems the most practical approach given the tensions between the need for flexibility and effectiveness discussed in the previous sections. Bridging the gap in the positions of different groups of delegates at the WIPO IGC is very challenging. Although the IGC was established sixteen years ago, the deliberations are far from agreement on a robust and substantive international instrument. In fact, some member countries on opposing sides seem to feel intense frustration with how the IGC process is progressing. The IGC had faced a crisis as its mandate failed to be renewed in 2014.

However, bringing countries together should not mean that every member of the IGC has to sign on to the proposed instrument. There will have to be a balance between setting up a system that most countries agree to and having some level of effective TK protection. Given the lack of domestic legislation in user countries regarding TK, adopting a Paris-like national treatment may not be adequate to provide enough incentive for TK codification and disclosure.

Therefore, a feasible path forward is for the Draft Articles to create a mandatory baseline protection made up of a few core provisions and principles based on the minimum consensus available within the IGC forum and to leave the details of the framework for domestic jurisdictions to address based on the socio-political and economic situations of the country. The preambular/introductory statements in the Draft Articles are a good place to start in creating consensus. As mentioned in the earlier section, the need to document and conserve TK is one of the few uncontested statements in the Draft Articles. As such, the international effort to set up an international treaty should focus on the need to encourage the codification and disclosure of TK as an organizing principle for the establishment of a framework. It is possible that most user

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757 Ibid at 256.


759 Saez, supra note 629.
countries might not agree to some of the principles and the scope of protection. In such a scenario user countries could build pressure by establishing a united front of like-minded megadiverse states that proposes organized and strategic policies and negotiating positions.\textsuperscript{760}

In terms of substantive provisions, the Draft Articles should include a few provisions that could encourage countries to provide effective TK protection within their jurisdictions. Given the purpose of these provisions, they will have to be somewhat general. It is proposed that the Draft Articles include five provisions on the following issues: A provision defining TK and the general subject matter that should be subject to protection (currently included in Article 1 of the Draft Articles); A new article requiring the establishment of domestic frameworks that would encourage the codification and disclosure of TK through databases/registries; an article setting out enforcement measures (Article 4); provisions on national treatment and MFN treatment (Article 11); and a provision on the relationship of the instrument to other international agreements (Article 10).\textsuperscript{761}

The instrument needs to define the subject matter of protection. This will be necessary if signatories are to be accountable for whether or not they have set up systems that would address the issue. The definition of TK provided in this dissertation\textsuperscript{762} seems to have considerable acceptance among members of the IGC. However, the definition provided does not have to be a detailed and rigid one. A non-exhaustive list of subjects that should be included in the definition of TK may suffice. In addition to defining TK, the purpose of TK protection – the codification

\textsuperscript{760} Field and Fisher suggest that source countries of genetic resources and TK show a united front against user firms to avoid a “race to the bottom” scenario. The proposal made in this section is similar to Field and Fisher’s proposal but it is proposed in terms of the global politics and negotiation between source countries and user countries. Martha A Field & William W Fisher, Legal reform in Central America: dispute resolution and property systems (Cambridge, Mass.: Distributed by Harvard University Press, 2001) at 255; A proposal for the need to create a biodiversity cartel was made by Vogel. This later proposal is similar to the one made in this section as it relates to global politics of using TK. See generally, Joseph H Vogel, “From ‘the Tragedy of the Commons’ to the ‘Tragedy of the Common Place’: Analysis and Synthesis Through the Lens of Economic Theory” in Charles McManis, ed, Biodivers Law Intellect Prop Biotechnol Tradit Knowl (London: Earthscan, 2007).

\textsuperscript{761} Carvalho proposes the establishment of only two provisions in an international TK instrument one that defines TK and another one that sets out enforcement mechanisms. Carvalho, supra note 3 at 265–266.

\textsuperscript{762} As stated in the first chapter, TK is defined in this dissertation as the know-how, skills, practices and learnings of indigenous peoples and local communities.
and disclosure of TK – will have to be set out in the instrument. The Draft Articles already have such a statement but expressed only as an aspirational/preambular term. Given the need to craft guidance to domestic legal systems the core purpose of protection may need to be explicitly stated.

The instrument will also have to require that there be some sort of effective enforcement measure that is not burdensome for knowledge holder communities or users. The details of the methods of enforcement to be adopted should be left for member countries to determine. There is a recent trend in which infringement of IP laws has been increasingly criminalized. However, this trend has been criticized because of the negative effect it might have on innovation and creativity. Given the uncertainties involved in using TK in ‘modern life,’ the provision of criminal sanctions does not seem warranted. The instrument could generally require that there be civil sanctions and provide policy space for countries to choose what measures to adopt in their domestic legal systems. These civil measures could include exclusive property rights requiring consent before access; a right of compensation; injunctive relief.

As discussed earlier, the principles of national treatment and most favored nation treatment are basic principles in international IP law. These are also issues that can only be dealt with in an international forum. Thus, they should be included in any international framework for TK protection. The instrument will also need to address what its relationship to existing and future international agreements should be. As highlighted earlier, this issue has become contentious and reaching a consensus might not be easy. However, it is an issue that needs to be addressed, and it has to be addressed in an international forum. A potential mid-way solution is for the instrument to take precedence in cases directly affecting TK protection and to defer to other instruments for issues that fall within that instruments’ core mandate. Potential conflicts between an international TK protection framework and other international instruments should not be overstated, however. Many potential conflicts could be resolved by interpreting instruments in light of the spirit of each legal framework. As a complementary measure, a dispute settlement mechanism could be

764 Carvalho, supra note 3 at 266.
established for the interpretation of conflicting provisions to address cases in which there are clear and unresolved conflicts.

5.2 The ‘Disclosure of Origin’ requirement

After first being mentioned in the Andean Community Decisions no. 391 (1996) and 486 (2000), the ‘disclosure of origin’ requirement has taken centre stage in the international deliberations on TK protection. The requirement began in discussions relating to genetic resources, but it has currently become one of the key topics discussed at the WIPO – IGC discussions in TK protection as well. As stated earlier in this chapter, the disclosure of origin requirement refers to the obligation that would be imposed on patent applicants to disclose the country of origin or source of TK or genetic resources used in the creating the invention. In some jurisdictions, the requirement includes an obligation to produce evidence showing that the applicant has complied with the laws of countries of origin or source relating to access to TK and genetic resources. Advocates believe the disclosure of origin requirement will provide an efficient system to regulate the relationship between TK holders and users.

The requirement has been adopted in many developing countries and some developed countries. Notably, the 1998 European Union Biotechnology Directive includes a voluntary system of disclosure of origin, in which patent applicants are encouraged, but not required, to disclose the origins of TK used in developing their invention. Furthermore, jurisdictions such as Belgium, Denmark, Germany, Sweden and Switzerland have adopted requirements for the disclosure of


767 Recital 27 of the directive states “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;” Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 30 July 1998 [EU Biotechnology Directive].
origin, while Norway has added the requirement of showing that Prior Informed Consent (PIC) under the law of the country of origin has been met.\textsuperscript{768} More recently, the EU has advocated the adoption of a mandatory disclosure of origin requirement.\textsuperscript{769} The Bonn Guidelines, discussed earlier, calls on countries to “take measures to encourage the disclosure of origin of genetic resources and of the origins of traditional knowledge.”\textsuperscript{770} Despite the popularity of the requirement among many countries, it remains contentious. Critics of the requirement cite several reasons for their objection including the considerable burden that inventors will be required to bear; the risk that adding new conditions for patent rights may reduce the incentivizing effect of patent rights; the lack of expertise of patent examiners and other issues related to feasibility.\textsuperscript{771} Proponents of the disclosure of origin requirement consider it to be part of a larger movement to make patent laws more responsive to the interests of developing countries and marginalized communities.\textsuperscript{772}

As highlighted earlier in this chapter, the ‘disclosure of origin’ discussions take place in many forums and particularly at the WIPO – IGC, CBD, and WTO meetings. However, delegates have yet to agree on core questions, which include: Should the requirement be mandatory or voluntary? Should disclosure be limited to information on sources or should it include a requirement to prove Prior Informed Consent (PIC) and benefit sharing agreement? How should association between TK, genetic resources and the invention be determined? What should be the penalty for non-compliance?\textsuperscript{773} A mandatory disclosure requirement that includes the obligation to disclose PIC and benefit sharing agreements is advocated in this chapter. A mandatory disclosure requirement is necessary because if patent applicants are allowed to disclose voluntarily the origin of TK, users that engage in intentional acts of biopiracy will not come forward and reveal their source of TK.

\textsuperscript{768} Medaglia, \textit{supra} note 766 at 3.
\textsuperscript{770} Secretariat of the Convention on Biological Diversity, \textit{supra} note 130 at Articles 16 (d, ii), 53 (b).
\textsuperscript{772} \textit{Ibid} at 148.
\textsuperscript{773} Medaglia, \textit{supra} note 766 at 3.
Voluntary disclosure requirement, therefore, will have little effect in encouraging TK holders to invest in codification. Furthermore, a requirement that includes disclosure of PIC and benefit sharing will empower source countries and communities by giving them a much-needed bargaining power in their relationship with users. As discussed throughout this dissertation, TK holders require some form of control over their codified TK. A disclosure requirement that includes evidence of PIC and benefit sharing would enable TK holders to assert such control.

In a research report on behalf of the United Nations Conference on Trade and Development (UNCTAD), Joshua Sarnoff and Carlos Correa provide a helpful commentary on what issues should triggers the obligation under the disclosure of origin requirement. They suggest the adoption of a broad substantive trigger which considers the “many types of inputs into the process of discovery of and application for the subject matter.” However, deciding which types of uses should trigger the disclosure of origin requirement is no easy task. A single invention could, and usually does, benefit from numerous pieces of information and it could rely on such information to varying degrees, which creates challenges for the enforcement of the disclosure of origin requirement. The EU’s position is that disclosure of TK should be required only when the patent applicant relied directly on such TK to develop the invention in question. However, excluding situations in which inventors rely on TK indirectly from the disclosure requirement may discourage TK holders from investing in codification by excluding a considerable portion of the relationship between TK holders and users. A more robust tool may be the ‘substantial reliance’ test adopted by William Fisher, in which patent applicants will be required to disclose the origin of TK if they relied, to a substantial degree, on such resource in the inventive process. ‘Substantial reliance’ is, however, a vague term in itself and, as Fisher himself acknowledges, will have to be interpreted by courts through litigation.

775 Ibid at ix.
776 Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications supra note 768 at 6 (Annex).
777 Fisher, supra note 532.
Sarnoff and Correa also provide some options for measures that could be adopted to incentivize compliance. These measures could be mixed to meet the policy objective of a particular jurisdiction. They include

(a) Curable or incurable, temporary or permanent bars to the processing of applications;
(b) Administrative fines, civil liability or criminal penalties;
(c) Termination, or full or partial transfer of entitlements to apply for or own intellectual property;
(d) Curable or incurable, temporary or permanent, full or partial unenforceability, revocation, narrowing of the subject matter, or invalidation of granted intellectual property;
(e) Return or transfer of benefits received from intellectual property; and
(f) Enforcement of existing or new obligations that provide for equitable benefit-sharing.\footnote{779}{Sarnoff \& Correa, supra note 774 at xi.}

The particular measure that should be adopted to encourage compliance should generally be left to countries to decide. Since remedies depend highly on the type of legal system and the overall legal environment in each jurisdiction, this is an issue better left to be addressed by each country. However, it may be helpful to provide some minimum requirements so that TK holders will have some remedy to leverage which could encourage investment in TK codification and disclosure. This may be ‘facultative’ measures that could respond to the actions of the patent applicant and could include temporary suspension for simple violations to patent revocation for the most egregious violations.\footnote{780}{Ibid.} Given the comprehensive nature and effectiveness of the TRIPs Agreement, amendment of the instrument to include a mandatory disclosure of origin requirement would be the best tool to establish an effective international system of TK protection.\footnote{781}{Field \& Fisher, supra note 760 at 256; Sarnoff \& Correa, supra note 774 at v.}
The disclosure of origin requirements fits well with the thesis for TK codification and disclosure discussed in this dissertation. One of the key challenges in the disclosure of origin requirement is the costs associated with such obligation and the burden that it will create for both administrative agencies and patent applicants. Codified and accessible TK can be expected to reduce such costs involved in disclosure given the systematic documentation of TK and the ease of access enabled by the proposed bioprospecting right. Furthermore, as argued in Chapter Three and four, investments from the private sector are essential to complement other means of support for TK codification and disclosure. If the disclosure of origin requirement is adopted, private actors such as biopharmaceutical firms that anticipate using TMK from a certain region would be incentivized to support TMK codification and disclosure efforts. A mandatory disclosure requirement that includes the requirement to provide that PIC and benefit sharing requirements have been met will strongly encourage TK holders to invest in TK codification and disclosure. TK holders will have the confidence that they will be able to share in the profits that may result from use of their codified TK by outsiders.

In addition to the ‘disclosure of origin’ requirement, there has been a proposal to have international instruments recognize national laws of source countries in relation to TK. Because of the originality of the proposal a detailed discussion of such proposal seems necessary. Although the proposal has not been included in the Draft Articles, if it is accepted into an international treaty, it has the potential for providing an effective solution to the challenges created by the territoriality of TK protection mechanisms without disrupting the international IP system. The proposal is discussed further below.

### 5.3 International Recognition of National Laws

As highlighted in the previous sections, one of the core disputes on the international protection of TK is determining which issues to address through an international treaty and which to leave for domestic jurisdictions to address. William Fisher argues that an international regime is not the answer. He instead proposes the insertion of a simple but potentially effective provision to the

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782 Sarnoff & Correa, *supra* note 774 at xiii.
TRIPs Agreement that would protect TK at the international level. Fisher proposes the insertion of the following provision to the TRIPs Agreement:

> It shall be a defense to a claim of patent infringement that the inventor(s), in developing the protected product or process, relied substantially upon materials or knowledge taken from a member country in violation of that country’s laws.

The brilliance of such an insertion is in its effect of giving back the power of regulating the use of TK to the source country. Since most megadiverse countries (and those that are net exporters of TK) have either already created systems of protection for TK or are in the process of doing so, the insertion of such a provision in the TRIPs agreement would cover most of the TK available globally. A common feature of these domestic laws in source countries is the requirement of the prior informed consent of a local government agency or knowledge holding community. Most of these laws also have requirements for benefit-sharing with source communities. Therefore, if the above provision is successfully inserted into the TRIPs agreement (or any other relevant agreement), it has the potential for addressing TK protection at the international level without the need for an independent agreement.

The other effective feature of this provision is that it would “give the local laws teeth, not by penalizing violations directly, but by exposing violators to the economically devastating sanction of the forfeiture of their own intellectual-property rights.” Under such a system, a patent right will not be invalidated because it violates the domestic law of a country from which the TK was

783 Fisher, supra note 778; Field & Fisher, supra note 760 at 256.
784 Fisher, supra note 532 at 132.
786 Fisher, supra note 532 at 133.
sourced. The effect of the provisions arises when a patent holder brings a patent infringement lawsuit against a defendant. The defendant can show as an affirmative defense that the patentee violated the domestic law of the country from which the patentee received TK that directly or indirectly helped in the making of the invention. The framework will use the considerable power of private incentives of defendants to make such a tool work effectively.

Fisher’s proposal for amendment of the TRIPs agreement by inserting provisions that recognize domestic laws of source countries is important for the bioprospecting rights framework discussed in the previous chapter. The risk of extra-territorial free-riding will be greatly reduced if the bioprospecting rights framework is adopted by source countries while such framework is recognized under an effective international instrument. Users will be required to comply with domestic bioprospecting rights frameworks in order to enforce their patents against potential infringers. The risk of losing the exclusivity of a patent right will encourage patent applicants to make sure that they have fulfilled the PIC and fair and equitable benefit-sharing requirements discussed under the bioprospecting rights framework.

A similar proposal was made by Nuno Pires de Carvalho in 2000. By citing US case law as an example, Carvalho identifies the application of the ‘unclean hands doctrine’788 in patent law in which a patentee who has abused his/her IP right or who has been fraudulent cannot seek relief from a court or similar entity until such abuse or fraud is addressed.789 This doctrine resembles the disclosure of origin requirement discussed in the previous section. Carvalho argues that the concealment of the use of TK in the development of an invention in patent applications could be declared as an abuse of IP rights under an international treaty.790 The effect of a patent right obtained through unclean hands is the temporary suspension of the right of the patentee to seek

789 Carvalho, supra note 787 at 399–400.
790 Carvalho, supra note 3 at 256.
redress against potential infringers. Once the patentee ‘cleans his/her hand’ by disclosing the origin of TK he/she is able to bring lawsuits against infringers. Carvalho’s proposal is made in the context of the defensive protection of TK.\(^{791}\) This application of the ‘unclean hands’ doctrine is similar to some of the forms in which the disclosure of origin requirement could be adopted. Carvalho’s proposal would result in an effective positive protection if it is also obligates patent applicants to fulfill PIC and benefit sharing obligations found in the laws of source countries.

In terms of the ‘bioprospecting rights’ framework developed in the previous chapter, if source countries adopt legislation that gives effect to such rights, the adoption of the ‘unclean hands doctrine’ or the insertion of the provision proposed above by Fisher may be a good starting point from which to establish a workable global framework of TK protection. If a treaty recognizes positive rights of knowledge holder communities in their codified TK and a user violates such rights and later claims patent rights in a country that is a member of such treaty, then the patentee will be exposing the patent to an effective defense. The greatest challenge faced by the proposals discussed above will thus be convincing developed countries in which most users reside to agree to such a mechanism. If the amendment or insertion is made in the TRIPs Agreement as proposed by Fisher, then the full force of the TRIPs Agreement will enable the emergence of an effective TK protection system at the international level, with the WTO dispute settlement regime available to ensure compliance.

To sum up this section, there is a need for an international TK protection system to strike a balance between providing effective protection for TK with sufficient flexibility for signatories to define what form TK protection will take in their domestic jurisdictions. A combination of some substantive minima with the basic principles of national treatment and MFN treatment may be capable of establishing such balance. A key substantive minimum is the requirement of disclosure of origin that includes the requirement of fulfilling PIC and benefit-sharing conditions of source countries. As a complementary measure, the recognition of domestic laws of source countries

\(^{791}\) As defined in the first chapter, defensive protection of TK is the prevention of users from receiving patent rights for inventions that have relied directly or indirectly on TK. It is contrasted to positive protection in which knowledge providers receive positive rights in their TK.
could be introduced in the TRIPs Agreement or other relevant international instrument in order to address the challenges of the territoriality of TK protection under domestic jurisdictions.

Now that the possible options for international TK protection have been analyzed, the following section will address the latest trend in international TK protection – bilateral investment treaties and free trade agreements. Following the general trend of countries utilizing bilateral and plurilateral mechanisms rather than multilateral negotiation to address global trade, proponents of TK protection have attempted to insert provisions on TK protection into bilateral investment treaties and free trade agreements. The following section examines the impact of using such instruments to protect TK and its potential effect in encouraging the codification and disclosure of such knowledge.

5.4 Protection through Free Trade Agreements (FTAs)

The latest development in the international movement to protect TK seems to lie in the realm of bilateral/plurilateral investment treaties and free trade agreements. Global Affairs Canada\textsuperscript{792} recently researched the recent trend of including TK related provisions (among others) in free trade agreements (FTAs).\textsuperscript{793} The result was a report on nearly 70 FTAs signed between countries that may be expected to have such provisions in their FTAs. Close to half of the FTAs examined included provisions regarding TK while the rest made no mention of them. The FTAs that include TK provisions tend to be the most recent ones which shows that the practice of inserting TK protection into FTAs is trending upwards. FTAs signed between 2013 and 2015 (the last year the study covered) are most likely to have TK provisions. The ‘non-exhaustive compendium’ of FTAs shows that most of these TK provisions are included in the intellectual property chapters of the agreements, while some are in the environmental chapter, in other chapters, in MOUs or letters of understanding.

\textsuperscript{792} Formerly ‘Foreign Affairs, Trade and Development Canada’

\textsuperscript{793} Global Affairs Canada, \textit{Non-Exhaustive Compendium of the Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions Provisions found in Free Trade Agreements}. (Copy with author).
This trend seems to be an adoption of a similar trend in international IP law in which obligations under the TRIPs agreement have been expanded through FTAs. The trend in the use of FTAs seems to be a forum shifting strategy used by the US and EU to heighten intellectual property protection globally.\footnote{See generally Susy Frankel, “Challenging Trips-Plus Agreements: The Potential Utility of Non-Violation Disputes” (2009) 12:4 J Int Econ Law 1023.} Forum shifting (regime shifting) is a strategy in which a country or a group of like-minded countries changes the forum in which an issue is being considered and where progress is not to its satisfaction to one which it expects will fulfill their interests.\footnote{John Braithwaite & Peter Drahos, eds, \textit{Global Business Regulation} (New York: Cambridge University Press, 2000), ch 24.} The result of forum shifting in the IP realm is a TRIPs-plus regime in which many countries in the world now provide more protection than is required under the TRIPs Agreement.

Some scholars have criticized the use of FTAs to create an international norm. A core criticism is that FTAs are used by powerful countries to bypass multilateral negotiation forums in order to create global norms that most other countries would not accept.\footnote{Jagdish N Bhagwati, \textit{Termites in the trading system: how preferential agreements undermine free trade} (New York: Oxford University Press, 2008) at 72; See generally, Pedro Roffe & Christoph Spennemann, “Preferential Trade Agreements and Intellectual Property Rights” in Mario Cimoli et al, eds, \textit{Intellect Prop Rights Leg Econ Chall Dev} (Oxford University Press, 2014); Daniel J Gervais & Frankel Susy, \textit{Advanced Introduction to International Intellectual Property} (Edward Elgar Pub, 2015) at 128; Frankel, supra note 794 at 1039.} In multilateral negotiations, countries with less bargaining power can form a coalition of like-minded countries in order to challenge more powerful actors to establish fair international standards acceptable by the majority of members. In bilateral and plurilateral agreements this power is greatly reduced and developing countries usually end up giving in to the demands of more powerful states.\footnote{See generally and page 11 - 12, Carlos Maria Correa, \textit{Intellectual property rights, the WTO and developing countries: the TRIPS Agreement and policy options} (Penang, Malaysia: Zed Books, 2000).} Although it has been understood that forum shifting is a practice used by powerful states and most frequently by the US,\footnote{Braithwaite & Drahos, supra note 795 at 565.} Laurence Helfner has argued that the advocates of international TK protection may have also used a forum shifting strategy in shifting from TRIPs to biodiversity and human rights forums in order to ensure the recognition of TK in international instruments.\footnote{Helfner Laurence, “Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law Making” (2004) 29 Yale J Int Law 1 at 46, 55.} By further moving
TK protection discussions into FTAs, developing countries may be attempting to yet again shift regimes in order to create norms and principles that they have been advocating unsuccessfully in other forums. Given the increase in the use of FTAs to further trade and IP policy, the question remains if the deman.deurs of international TK protection, which are usually countries with weaker bargaining power, can use FTAs to further their cause.

This is the question that Susy Frankel responds to in her 2012 publication “Attempts to Protect Indigenous Culture through Free Trade Agreements.” Frankel finds that the deman.deurs of international TK protection are not using FTAs to establish norms around TK protection. She finds, rather, that TK provisions in FTAs that have them “purport to reserve the right of the parties to protect [TK] or they have mere aspirational statements about the parties agreeing to discuss the protection of [TK].” Such vague and general terms will not be able to establish norms regarding the international protection of TK. To date, lead deman.deurs of international TK protection such as India, South Africa, and Egypt have not included TK provisions in their FTAs.

In some instances, the deman.deurs of international TK protection actually agree to terms that undo the progress made on the IGC front by giving into the position of a more powerful party. The FTAs signed by Peru with other countries is a prime example of this. Among the countries included in the Global Affairs Canada research, Peru stood out as a leader in having TK provisions included in FTAs. In fact, Peru’s FTA with the European Free Trade Association has one of

800 Frankel, supra note 667.
801 Ibid at 127.
803 See annex to of this dissertation, Global Affairs Canada, supra note 793; Email communication with Nadine Nicker, Senior Trade Policy Officer, Intellectual Property Trade Policy Division (TMI), Global Affairs Canada. Nadine Nicker, Follow Up (2015).
804 Frankel, supra note 667 at 127.
805 See FTAs signed by Peru, Global Affairs Canada, supra note 793.
the strongest requirements on disclosure of the origins of TK in patent applications.\textsuperscript{806} However, in the FTA Peru signed with the United States, the memorandum of understanding on TK, states that the parties agree that TK protection “can be adequately addressed through contracts.”\textsuperscript{807} This position is the same as that the United States took in discussions of TK protection through WTO’s TRIPs agreement.\textsuperscript{808} Peru’s strong advocacy for TK protection, which is reflected in FTAs it has with other countries and in other international forums, is not reflected in its MOU with the US. This example of the Peru-USA FTA might be evidence of how weaker countries can be more disadvantaged under bilateral agreements than in multilateral settings.

However, what is more striking is that some FTAs between \textit{demandeurs} of international TK protection have also failed to provide strong norm-setting provisions on TK protection.\textsuperscript{809} This is the case even if both sides of the FTA have commonalities in TK protection domestically.\textsuperscript{810} This is the case, for instance, with the Peru-China FTA. The wordings in these FTAs are aspirational or permissive at best. These scenarios speak to a missed opportunity that \textit{demandeurs} of TK protection have to further entrench the international norms surrounding TK protection being developed at the IGC.\textsuperscript{811} Although limited in their impact, TK protection norms included in FTAs between \textit{demandeurs} of TK protection have the potential to influence multilateral deliberations.

\textsuperscript{806} “The Parties, in accordance with their national laws, shall provide for administrative, civil or criminal sanctions if the inventor or the patent applicant wilfully make a wrongful or misleading declaration of the origin or source. The judge may order the publication of the ruling.” Article 6.5 (6) \textit{Free Trade Agreement between the Republic of Peru and the European Free Trade Agreements (EFTA) States} (2010); Email communication with Nadine Nicker, Senior Trade Policy Officer, Intellectual Property Trade Policy Division (TMI), Global Affairs Canada. Nickner, \textit{supra} note 803.

\textsuperscript{807} \textit{The United States - Peru Trade Promotion Agreement, Memorandum of Understanding Regarding Biodiversity and Traditional Knowledge} (2006).

\textsuperscript{808} Frankel, \textit{supra} note 667 at 128.

\textsuperscript{809} Many of the FTAs signed by Peru and India with other Asian and Latin American countries do not have TK protection at all. Some of the FTAs that have TK protection have general statements that are not able to qualify as norm-setting. Global Affairs Canada, \textit{supra} note 793.

\textsuperscript{810} See discussion following note 47 regarding the Peru-China FTA, Frankel, \textit{supra} note 48 at 129.

\textsuperscript{811} \textit{Ibid} at 133.
5.4.1 The Trans-Pacific Partnership Agreement

The dynamics between countries with different bargaining power under FTAs can also be seen in the difference between one of the latest and most controversial agreements – the Trans-Pacific Partnership Agreement (TPP)\(^{812}\) and its precursor agreement, the Trans-Pacific Strategic Economic Partnership.\(^{813}\) The initial agreement, the Trans-Pacific Strategic Economic Partnership, was signed between Brunei, Chile, Singapore and New Zealand. It included a permissive but clear statement on TK protection. The agreements under its Chapter 10, Article 10.3 states: “Subject to each Party’s international obligations the Parties affirm that they may: … (d) establish appropriate measures to protect traditional knowledge.”\(^{814}\) More important, the founding countries of the agreement included TK in their definition of “creative arts.”\(^{815}\) This may be an example of a ‘legal innovation’\(^{816}\) in which countries favorable to TK protection are attempting to use FTAs to re-define key international IP terms in the absence of powerful states objecting to TK protection. Given this background, the changes in the later agreement – the Trans-Pacific Partnership (TPP), which includes more powerful states such as the US, Japan, Australia and Canada - shows a shift towards weaker and generalized statements on TK protection.

The TPP addresses TK in two different chapters: its intellectual property chapter (Chapter 18) and environmental chapter (Chapter 20). It has been noted that the United States and Japan were against the inclusion of statements on TK protection under the IP chapter.\(^{817}\) This may arguably

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\(^{812}\) Trans-Pacific Partnership Agreement (2016). Member countries of the agreement are: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States of America and Vietnam.


\(^{814}\) Chapter 10, Article 10.3 (d) ibid.

\(^{815}\) See note accompanying Chapter 19, Article 19.1 (3) ibid. It should be noted that the definition provided focuses on literary and artistic fields which are different from the definition of TK provided under this dissertation. However, given the interest of advocates of TK protection to define TK holistically, the definition used in this agreement may still apply to TK as defined in this dissertation.


\(^{817}\) Haugen, supra note 802 at 81.
be a strategy used by the US and Japan (countries that are usually against strong TK protection) to avoid the inclusion of TK as intellectual property independent of genetic resources. As discussed in Chapter One, TK relevant for the conservation of biodiversity and genetic resources is a subject covered under the CBD. The WIPO IGC forum deliberates on TK protection as a stand-alone issue. If, as the US and Japan wanted, TK protection was excluded from the IP chapter, TK would not have been discussed as an independent intellectual property issue at the WIPO IGC. TK discussion would have been exclusively on TK that is relevant for biodiversity conservation, as is the case under the CBD framework. As discussed below, the final wording of the provisions of the IP chapter still avoids using the term TK independently.

The TPP Article 18.16 descriptively titled “Cooperation in the Area of Traditional Knowledge” has three sub-articles, two of which make very general statements about TK.\footnote{The third sub-article simple focuses on defensive protection of TK by increasing the quality of patent examinations through increased access to TK.} The first sub-article states that signatories “recognise the relevance of intellectual property systems and traditional knowledge associated with genetic resources […]” while the second sub-article states that “Parties shall endeavour to cooperate […] to enhance the understanding of issues connected with traditional knowledge associated with genetic resources [...]”\footnote{Chapter 18, Article 18.16 note 812.} These provisions do not commit signatories to any particularly enforceable obligation, nor do they include any of the basic principles being discussed at the WIPO IGC. The basic principles of prior informed consent and access and benefit sharing have not been recognized. Despite the focus of the third sub-article on increasing the ‘quality of patent examination,’ it does not require patent applicants to disclose information regarding any TK used in the development of the invention. The IP chapter has avoided mentioning all major principles being considered under international TK protection.

In fact, given that TK is mentioned only as it relates to genetic resources, the provisions seem to refer to the general obligations under the CBD and completely neglect the IGC deliberations on TK protection independent of genetic resources. In addition to the weakness of these provisions, cooperation on any issue in the chapter is based on the “availability of resources, and on request,
and on terms and conditions mutually agreed upon between the Parties involved."\textsuperscript{820} Since the article on TK calls for ‘cooperation’ on the issue, all of the statements are conditional on this provision, further weakening any statement made about TK protection.

The TK discussions under the environmental section are similar to those in the intellectual property chapter. Article 20.13 of the chapter titled ‘Trade and Biodiversity’ mostly focuses on genetic resources. Sub-article 3 of the same article states:

\begin{quote}
The Parties recognise the importance of \textbf{respecting, preserving and maintaining} knowledge and practices of indigenous and local communities \textit{embodying traditional lifestyles that contribute to the conservation and sustainable use of biological diversity}.\textsuperscript{821} [Emphasis added]
\end{quote}

The quoted text does not say anything about ‘protection’ of TK as parties only agreed to recognize the need to ‘respect, preserve and maintain’ TK. This provision is almost identical to Article 8(j) of the Convention on Biodiversity (CBD).\textsuperscript{822} However, the CBD provision goes on to state that the parties agree to promote access and benefit sharing with indigenous peoples and local communities while the TPP’s version has a much-weakened version of the commitment focusing only on genetic resources.\textsuperscript{823} Overall, the TK provisions in both the IP and environment chapters of the TPP do not contain any clear commitments or obligations. They also do not recognize the advanced deliberations at the WIPO IGC on TK protection as an independent subject matter.

\begin{footnotes}
\item[820] Chapter 18, Article 18.17 \textit{ibid.}
\item[821] Chapter 20, Article 20.13 (3), \textit{ibid.}
\item[822] Article 8 (j) \textit{The Convention on Biological Diversity, supra} note 638.
\item[823] Chapter 20, Article 20.13 (4) note 812“The Parties recognise the importance of facilitating access to genetic resources within their respective national jurisdictions, consistent with each Party’s international obligations. The Parties further recognise that some Parties require, through national measures, prior informed consent to access such genetic resources in accordance with national measures and, where such access is granted, the establishment of mutually agreed terms, including with respect to sharing of benefits from the use of such genetic resources, between users and providers.” [Emphasis mine]
\end{footnotes}
The history of the negotiating dynamics of the TPP could be seen from leaked text of earlier versions of the TPP.\textsuperscript{824} Peru, Malaysia, Mexico and Brunei proposed strong obligatory and detailed commitments in earlier versions of the TPP agreement, while countries such as New Zealand, Australia, and Canada have opposed the use of such terms and preferred more permissive statements.\textsuperscript{825} The general divide discussed in the earlier section between the positions of developing countries that hold considerable TK within their jurisdiction and developed countries where most users reside is seen in these negotiating documents. Given the highly qualified, non-obligatory and general statements on TK protection in the final text, it can be concluded that more powerful/developed countries have succeeded in restricting TK protection to a more aspirational and optional framework.

Although there have been several missed opportunities, analysis of the most recent FTAs shows that there might be an upward trend. Examination of a compendium of close to 70 FTAs prepared by Global Affairs Canada reveals that most of the leading countries that have pushed for TK protection globally have managed to insert TK related provisions into FTAs. This trend is seen especially in FTAs signed between 2013 and 2015, thus demonstrating a growing trend. For instance, the 2013 FTA between EU, Peru, and Colombia contains the most extensive commitment among the FTAs analyzed.\textsuperscript{826} While TK protection is discussed in both the environmental section and the intellectual property section, the provisions explicitly cite the rights and obligations of the parties to the CBD and other international forums. The provision’s relatively strong statements on the basic principles of ‘prior informed consent’ and ‘benefit sharing’ have been discussed in other forums. On other more recent FTAs, China has shown increasing success in inserting TK provisions into its FTAs, including those with Switzerland\textsuperscript{827}

\textsuperscript{825} See proposals and objections in Article QQ.E.23, \textit{ibid}.
\textsuperscript{826} Articles 201, 271 \textit{Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part} (2012).
\textsuperscript{827} Article 11.9 \textit{Free Trade Agreement Between the Swiss Confederation and the People’s Republic of China}. 
and South Korea (2015)\textsuperscript{828} which expressly recognize the above mentioned basic principles.\textsuperscript{829} One conclusion that may be drawn from this trend may be that advocates of TK protection are finally realizing the potential of FTAs as norm-setting tools on a global level and have begun using them as such. However, since the practice is very recent, the actual impact of this trend remains uncertain.

A useful comparison to the TPP is an FTA thought by many to be an alternative to the TPP – The Regional Comprehensive Economic Partnership (RCEP). The RCEP has 16 member countries including China, but excluding the US.\textsuperscript{830} The leaked text of the IP chapter in the RCEP shows strong substantive provisions on TK protection.\textsuperscript{831} Although the RCEP is still being negotiated, if the final text manages to include most parts of the current provisions, it will set a much stronger standard of TK protection than that set by the TPP.

To summarize the above discussion, although FTAs are not the ideal route to the creation of international norms, for one reason or another, there is a proliferation of such agreements. FTAs are being signed by states in varying stages of economic development. Each member of the WTO is thought to be a signatory to an average of 13 FTAs.\textsuperscript{832} Given that they have become ubiquitous, the \textit{demandeurs} of international TK protection should start using FTAs strategically to build norms around basic principles that signatories would accept.\textsuperscript{833} A promising trend is that the

\textsuperscript{828} Article 15.17 \textit{Free Trade Agreement between the Government of the People\textquotesingle s Republic of China and the Government of the Republic of Korea}.  
\textsuperscript{829} Notably, China\textquotesingle s FTA with Australia (2015) (which was signed at the same time as its FTAs with Switzerland and South Korea) only has aspirational statements which shows that it is also finding it hard to negotiate the inclusion of strong TK protection norms in FTA agreements with an economically developed country. See Article 11.17 \textit{Free Trade Agreement Between the Government of Australia and the Government of the People\textquotesingle s Republic of China}.  
\textsuperscript{830} Currently, the member countries of the RCEP are the 10 ASEAN countries and China, India, Australia, Japan, New Zealand and South Korea.  
\textsuperscript{831} See section 7 of the intellectual property chapter. \textit{Regional Comprehensive Economic Partnership (RCEP) (Leaked IP Chapter)} (Knowledge Ecology International).  
\textsuperscript{833} See generally Frankel, \textit{supra} note 667.
general value of TK is increasingly being recognized in many instruments and forums. Many FTA side letters (which are used as commitments between parties to continue deliberating on certain issues for the future), including some TPP side letters, deal with TK protection. Perhaps this is the beginning of the development of global norms on TK protection through FTAs. Delegates should build on general points of agreement in order to reach acceptable solutions. As discussed above and throughout the dissertation, the alarming rate of TK loss and the need to establish legal frameworks that encourage its codification and disclosure should be the organizing principles in such endeavor.

6 Conclusion

The previous chapter outlined a legal framework that countries may adopt in their domestic jurisdictions in order to encourage the codification and disclosure of TMK. The risk of extra-territorial free-riding, however, suggests the need for an international protection mechanism. Although some domestic measures such as secrecy and deferred disclosure could mitigate the effect of free-riding, they are not ideal tools. Secrecy and deferred disclosure limit the dissemination of TK resulting in inefficiencies. The full potential of the legal framework will be realized only when there is an international TK protection mechanism.

The chapter examined the status quo in terms of relevant international fora that have implications for TK protection with emphasis on the WIPO, CBD and WTO. It also examined the most advanced instrument on TK protection – the Draft Articles of the WIPO IGC. Although international TK protection has been discussed for over a decade, a clear and enforceable regime of protection has yet to be achieved. International deliberations at the WIPO IGC are stalled because of the failure of delegates to agree on several key issues. These issues include the

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834 Haugen, supra note 802 at 92.
835 See side letters of the TPP, Understanding Regarding Biodiversity and Traditional Knowledge (The Government of Canada and the Government of Malaysia); Understanding Regarding Biodiversity and Traditional Knowledge (The Governments of Canada and of the Republic of Peru); Bilateral Understanding between the U.S. and Peru on Biodiversity and Traditional Knowledge (2016); Understanding Regarding Biodiversity and Traditional Knowledge (The Governments of New Zealand and the Republic of Peru).
definition/scope of TK, the legal nature of the proposed instrument, the tension between providing flexibilities for domestic policy space and crafting an effective/enforceable system of protection, and the relationship between the proposed instrument and other international agreements. Negotiations are ongoing at the WIPO IGC despite these differences in negotiating positions.

The feasible way forward for international TK protection seems to lie in striking the right balance between providing flexibilities for domestic jurisdictions to craft domestic laws based on a country’s needs and capabilities, and ensuring that there is sufficient international obligation that would encourage the codification and disclosure of TMK. Such a framework should begin with the minimum consensus among key stakeholders in the global bioprospecting field.

In order to guide the development of such consensus and to strike a balance between flexibility and enforceability, it is proposed that the Draft Articles include five provisions on the following issues: A provision defining TK and the general subject matter that should be subject to protection (currently included in Article 1 of the Draft Articles); a new article requiring the establishment of domestic frameworks that would encourage the codification and disclosure of TK through databases/registries; an article setting out enforcement measures (Article 4); provisions on national treatment and MFN treatment (Article 11); and a provision on the relationship of the instrument to other international agreements (Article 10). The international instrument should be limited to these few provisions and it should leave the details of the system for domestic laws.

While diplomatic negotiations are painfully slow, scholars have advanced several proposals that seek to provide innovative legal tools to protect TK. The chapter has examined the feasibility of some of the most promising proposals and their implications for the codification and disclosure of TMK. The establishment of a mandatory disclosure of origin requirement that includes obligations to disclose PIC and enforceable benefit sharing agreements will be a key legal tool to provide effective international TK protection. Additionally, the recognition of national legislation under international agreements seems to have potential for establishing an effective form of international protection if the relevant international agreements such as TRIPs are amended to include such provisions. The basic principles of national treatment and most favored nation
treatment borrowed from international IP law are also needed in order to supplement minimum substantive protection.

Because of the lack of progress in multilateral regimes including that at the WIPO IGC, some demandeurs of international TK protection have begun using FTAs to further the international dialogue on TK protection. Although FTAs are not the ideal tool for establishing global norms, given that they are proliferating, countries advocating for TK protection should begin to use them strategically to establish global norms of TK protection. Although most demandeurs of TK protection do not have the bargaining power to influence more powerful countries, they could begin by inserting TK protection provisions into FTAs between two or more like-minded countries. In all of these efforts, it is suggested that the need to encourage the codification and disclosure of TK should be the organizing principle. Since this need has been endorsed in many instruments, including the WIPO Draft Articles, it should be possible to develop a global norm around such principles.
THESIS CONCLUSION

The literature on TK protection is strongly dominated by equity and distributive justice rationales for legal intervention. There is limited discussion of economic efficiency reasons for the legal protection of TK. One of the key contributions of this dissertation is, therefore, the examination of economic efficiency rationales for TK protection. TK is analyzed as a public good which has non-rivalrous and non-excludable characteristics. Consequently, it requires some form of government intervention for optimal production (i.e. codified and accessible TK). The public goods literature in general and the ‘knowledge as a global public good’ scholarship in particular offer strong economic efficiency rationales for TK protection.

TK is facing an alarming rate of loss as a result of the combined effect of the lack of codification, the extinction of TK holder communities, and a rising protectionist trend among source communities and countries. The predominantly oral nature of TK increases the risk of loss. When TK holding members of communities die, their knowledge dies with them. A rise in protectionist trend, where TK holder communities and mega-diverse countries are increasingly becoming restrictive in granting access to TK, adds to this risk. Because of the restrictions, TK is not used by outsiders. This fact combined with the destruction of TK holder communities exacerbates TK loss.

The alarming rate of loss can be explained in terms of the public good literature. Because TK has non-rivalrous and non-excludable qualities, TK holders would not invest in its codification and disclosure knowing that they will not have control over the knowledge post-codification. There are several alternative ways in which public goods are produced. While some of these alternatives work for TK, others do not. Secrecy, government provision and the recognition of private rights are some of the alternatives with potential to support TK production. They are, thus, complements to the framework proposed in this dissertation. Other alternative channels for the production of public goods, such as group cooperation, lead time (first-mover advantage), and charities, have little potential in the case of TK. These alternatives fail to support a robust system of TK codification because of the unique features of TK. Group cooperation does not seem to have significant potential because the close-knit social structure that is at the heart of group cooperation
is absent in most cases of TK use. Lead time or the first-mover advantage that provides sufficient incentives for the private production of public goods has little potential for TK because most TK can be easily copied and understood. Although charities can facilitate some TK production, because TK lacks a unifying interest that is dominant in public good production through charities, they often have little potential for TK. The purpose of the public goods analysis of TK is to extract important policy implications. The major public policy points that should be noted in the establishment of TK protection are the fact that there is an urgent need to address the alarming rate of TK loss with a focus on TK codification; the need for global collaboration in order to address such global public goods; and the need to strike the right balance between the interests of knowledge providers and users to establish a sustained and efficient framework.

An obvious mechanism to address this dramatic rate of loss is the codification and disclosure of TK. However, because of the public goods nature of TK, knowledge holders will not be able to recoup their costs of documentation and disclosure. Communities cannot reasonably be expected to make considerable investments in codifying their knowledge and disclosing it to outsiders without some protection or incentive. Legal intervention can address this disincentive by enabling TK holders to control what happens to their knowledge post-codification. It posits that a carefully crafted legal mechanism will encourage TK holder communities to invest in the codification and disclosure of TK, thereby saving the body of knowledge from the alarming rate of loss it is faced with. The chapter is also a call to stakeholders for a shift in paradigm from focusing on cultural conservation as the key objective to knowledge codification. It argues that the incentive that knowledge holder communities need is to codify their predominantly orally-transmitted knowledge and not to conserve their culture in its authentic form. The need to encourage TK codification and disclosure through legal intervention is proposed in this dissertation as a rationale that can build consensus among key stakeholders. It is, thus, proposed as the ideal organizing principle for TK protection.

The dissertation makes an analogy to patent laws to support the claim that legal intervention encourages knowledge codification. Since the many features of patent laws have been shown to encourage inventors to codify knowledge that they would otherwise not codify, a similar legal intervention has the potential to do the same for TK. Four key benefits of TK codification are identified, which are: the potential of codification to establish a common code for the
communication of TK to different communities; the preservation of TK from the alarming rate of loss it faces; the potential of legal protection in creating certainty with regard to the rights and responsibilities of stakeholders; and the notice and evidentiary function of TK codification.

There are, however, some criticisms of TK codification. A potential limitation of a market-based incentive may be that some TK that may not have a readily commercial value may not be codified. However, market provision of TK is expected to be complemented by public sources of support such as government investment in the codification of TK that may not have a readily available commercial value. The chapter also examines other potential limitations that TK codification may have including the prohibitive costs of documenting all of the TK that a community might hold, the risk of unauthorised public access to codified TK, and the disruption that codification may cause to cultures that have been isolated from mainstream communities. Rather than being reasons to reject codification, however, these limitations call for a robust legal mechanism for TK codification. The full use of technological advancements in TK codification will ensure the establishment of a system that reflects the needs of TK holders and users. To be most effective and sustainable, TK codification projects should take into consideration the interests of TK holders and users.

By focusing particularly on TMK, the dissertation argues that a carefully crafted ‘bioprospecting right’ regime can address this disincentive by enabling TMK holders to benefit from their codification and disclosure. TK holders or their representatives who codify and disclose TMK after receiving consent from knowledge holder communities will obtain a bioprospecting right over such knowledge. This right will include one of the following depending on the type of TMK database in which it is codified: 1) an exclusive right to conduct research or a right to share benefits from bioprospecting on TMK codified in a publicly accessible database; or a right to receive compensation for unauthorized access of TMK documented in a restricted database. The right would have four core requirements: 1) applicants should be TK provider communities or their licensees; 2) the applicant, if a licensee, must enter into a fair and equitable benefit sharing agreement; 3) the scope of the claimed TK should be clearly stated in the codification; 4) the claim TK should not be one that is already widely diffused. Such a requirement will balance the interests of both TK providers and users.
There would be two types of TK codification, a publicly accessible database, and a restricted database. The restricted database would only be accessible to TK holders and their licensees. These two types of codifications are intended to respond to the diverse interest of TK holding communities. TK holders interested in openly commercializing their TK can use the publicly accessible database, while those who prefer to keep it a secret, for whatever reason, will use the restricted database.

The dissertation examines possible terms for the bioprospecting rights. While providing specific term proves to be challenging, the dissertation examines the key factors that policy makers should consider in designing the scope of the right. The nature and scope of codification that will be subject to the proposed bioprospecting right are also examined. A holistic codification which systematically documents TK together with its socio-cultural and environmental context is advocated in this dissertation. In addition to making the codification more useful to bioprospecting purposes, holistic codification may have added value in anthropological and sociological terms.

Extra-territorial free-riding on codified TK is a serious risk in the proposed legal framework. Firms in jurisdictions that do not establish the framework could access publicly accessible TK databases and compete unfairly with firms in jurisdictions that have such framework, and in which firms are required to share benefits with TK holders. While there are domestic measures, such as secrecy and deferred disclosure, which can mitigate this risk, the full potential of the framework will only be realized through the establishment of international protection. Several international forums have deliberated about TK protection, including the WIPO, CBD, and WTO (TRIPs). However, delegates have not reached an agreement on whether TK should receive legal protection and what form such protection should take. The most advanced and comprehensive discussion on TK is taking place at the WIPO IGC. Although the ‘Draft Articles on the Protection of Traditional Knowledge’ have been passionately debated for several years, there is still considerable gaps in the positions delegates adopt. The fate of the Draft Articles is, therefore, quite unclear.

If an international framework of TK protection is to work, it has to be based on a consensus between mega-diverse countries and key countries in which most users reside. To build such a consensus, delegates should focus on minimum substantive standards on which they can agree.
These minimum standards should be used to build a baseline protection at the international level. This baseline protection should include provisions dealing with a definition of TK, provisions encouraging codification and disclosure, a provision on enforcement measures, national treatment and MFN treatment provisions and a provision addressing the relationship of the TK protection instrument with other international laws. The details of the framework and ways to implement the international standard within the domestic system should be left for the countries to decide on their own. In this context, the principles of national treatment and MFN treatment should be adopted as minimum substantive protections.

Additionally, a disclosure of origin requirement which requires patent applicants to disclose TK used in the process of developing the claimed invention should be adopted. This requirement should also include the obligation to produce evidence of Prior Informed Consent (PIC) and fair and equitable benefit-sharing. A similar system that has the potential to create consensus is the international recognition of domestic laws. This system will protect source countries that have domestic laws regarding access and benefit-sharing of TK. The bioprospecting right outlined in the dissertation will benefit significantly from the adoption of these frameworks. If source countries have adopted the proposed framework, and there is a disclosure of origin requirement and/or international recognition of domestic laws, the effect of the domestic legislation will be global, thereby addressing the risk of extra-territorial free-riding. Lastly, FTAs have the potential to support international TK protection. Demandeurs of TK protection can use FTAs to develop international norms around TK protection. Even if FTAs are not the ideal tools for international norm development, since they are gaining in popularity and since their scope is ever expanding, source countries should negotiate strong norms on TK protection.

In both domestic and international frameworks, it has been argued in this dissertation that the need to encourage the codification and disclosure of TK should be the organizing principle. As argued in this thesis, such a principle has the potential to bring new and key stakeholders to deliberations that could support TK protection. Additionally, the need to codify TK has been acknowledged by both TK holders and users. Many international forums, including the WIPO IGC, acknowledge the need to save TK from further loss.
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Appendices

Appendix 1: WIPO-IGC: The Protection of Traditional Knowledge: Draft Articles (See next page)
Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Twenty-Eighth Session

Geneva, July 7 to 9, 2014

THE PROTECTION OF TRADITIONAL KNOWLEDGE:

DRAFT ARTICLES

Document prepared by the Secretariat

1. The WIPO General Assembly in 2013 decided that the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) will “continue to expedite its work with open and full engagement, on text-based negotiations with the objective of reaching an agreement on a text(s) of an international legal instrument(s) which will ensure the effective protection of GRs, TK and TCEs” and that “the focus of the Committee’s work in the 2014/2015 biennium will build on the existing work carried out by the Committee and use all WIPO working documents, including WIPO/GRTKF/IC/25/5, WIPO/GRTKF/IC/25/6 and
WIPO/GRTKF/IC/25/7 which are to constitute the basis of the Committee’s work on text-based negotiations, as well as any other textual contributions by members.”

2. At its Twenty-Seventh Session, which took place in Geneva, from March 24 to April 4, 2014, document WIPO/GRTKF/IC/25/6, was made available as document WIPO/GRTKF/IC/27/4. The IGC developed, on the basis of that document, a further text, “The Protection of Traditional Knowledge: Draft Articles Rev. 2”. It decided that this text, as at the close of its discussions on “Traditional Knowledge”, under agenda item 6, on March 28, 2014, be transmitted to the WIPO General Assembly taking place in September 2014, “subject to any agreed adjustments or modifications arising on cross-cutting issues at the Twenty-Eighth Session of the IGC in accordance with the IGC’s mandate for 2014-2015 and the work program for 2014, as contained in document WO/GA/43/22”.

3. The text “The Protection of Traditional Knowledge: Draft Articles Rev. 2”, as developed during the Twenty-Seventh Session of the Committee, is annexed to the present document.

4. The Committee is invited to review the document contained in the Annex, in accordance with its 2014-2015 mandate, its work program for 2014 and the decision on agenda item 6 during its Twenty-Seventh Session referred to above.

[Annex follows]
PREAMBLE/INTRODUCTION

Recognize value

(i) recognize the [holistic] [distinctive] nature of traditional knowledge and its [intrinsic] value, including its social, spiritual, [economic], intellectual, scientific, ecological, technological, [commercial], educational and cultural value, and acknowledge that traditional knowledge systems are frameworks of ongoing innovation and distinctive intellectual and creative life that are [fundamentally] intrinsically important for indigenous [peoples] and local communities and have equal scientific value as other knowledge systems;

Promote awareness and respect

(ii) promote awareness and respect for traditional knowledge systems; for the dignity, cultural [integrity] heritage and intellectual and spiritual values of the traditional knowledge [holders]/[owners] who conserve, develop and maintain those systems; for the contribution which traditional knowledge has made in sustaining the livelihoods and identities of traditional knowledge [holders]/[owners]; and for the contribution which traditional knowledge [holders]/[owners] have made to the [conservation of the environment] conservation and sustainable use of biodiversity, to food security and sustainable agriculture, healthcare, and to the progress of science and technology;
Alternative

(ii) promote respect for traditional knowledge systems, for the dignity, cultural integrity and spiritual values of the traditional knowledge holders who conserve and maintain those systems;

[End of alternative]

Promote [conservation and] preservation of traditional knowledge

(iii) promote and support the [conservation of and] preservation [of] [and respect for] traditional knowledge [by respecting, preserving, protecting and maintaining traditional knowledge systems [and providing incentives to the custodians of those knowledge systems to maintain and safeguard their knowledge systems]];

Consistency with relevant international agreements and processes

(iv) take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that relate to intellectual property and access to and benefit sharing from genetic resources which are associated with
that traditional knowledge;

Promote access to knowledge and safeguard the public domain

(v) recognize the value of a vibrant public domain and the body of knowledge that is available for all to use, and which is essential for creativity and innovation, and the need to protect, preserve and enhance the public domain;

Document and conserve traditional knowledge

(vi) contribute to the documentation and conservation of traditional knowledge, encouraging traditional knowledge to be disclosed, learned and used in accordance with relevant customary practices, norms, laws, and/or understandings of traditional knowledge holders, including those customary practices, norms, laws and/or understandings that require prior informed consent or approval and involvement and mutually agreed terms before the traditional knowledge can be disclosed, learned or used by others;

Promote innovation

(vii) [the protection of traditional knowledge should] contribute toward the promotion of innovation and to the transfer and dissemination of knowledge to the mutual advantage of holders and users of traditional knowledge and in a manner
conducive to social and economic welfare and to a balance of rights and obligations;

Provide new rules and disciplines

(viii) [recognize the need for new rules and disciplines concerning the provision of effective and appropriate means for the enforcement of rights relating to traditional knowledge, taking into account differences in national legal systems;]

Relationship with customary use

(ix) not restrict the generation, customary use, transmission, exchange and development of traditional knowledge by the beneficiaries, within and among communities in the traditional and customary context, [in accordance with national law].

POLICY OBJECTIVES

This instrument should aim to:
Provide Indigenous [Peoples] and [local communities] [and nations]/[beneficiaries] with the [legal and practical/appropriate] means, [including effective and accessible enforcement measures/sanctions, remedies and exercise of rights], to:

a. [prevent] the [misappropriation/misuse/unauthorized use/unfair and inequitable uses] of their traditional knowledge;

b. [control ways in which their traditional knowledge is used beyond the traditional and customary context;]

c. [promote [the equitable sharing of benefits arising from their use with prior informed consent or approval and involvement or approval and involvement]/[fair and equitable compensation], as necessary; and]

d. encourage [and protect] [tradition-based] creation and innovation.

[Prevent the grant of erroneous intellectual property/[patent rights] over [traditional knowledge and [[traditional knowledge] associated [with] genetic resources].]]

USE OF TERMS

For the purposes of this instrument:

[Misappropriation means

Option 1

any access or use of the [subject matter]/[traditional knowledge] without prior informed consent or approval and involvement and, where applicable, without mutual agreed terms, for whatever purpose (commercial, research, academic and technology transfer).]
Option 2

is the use of protected traditional knowledge of another where the [subject matter]/[traditional knowledge] has been acquired by the user from the holder through improper means or a breach of confidence and which results in a violation of national law in the provider country, recognizing that acquisition of traditional knowledge through lawful means such as independent discovery or creation, reading books, receiving from sources outside of intact traditional communities, reverse engineering, and inadvertent disclosure resulting from the holders’ failure to take reasonable protection measures is not [misappropriation/misuse/unauthorized use/unfair and inequitable uses.]

[Misuse may occur where the traditional knowledge which belongs to a beneficiary is used by the user in a manner that results in a violation of national law or measures endorsed by the legislature in the country where the use is carried out; the nature of the protection or safeguarding of traditional knowledge at the national level may take different forms such new forms of intellectual property protection, protection based on principles of unfair competition or a measures-based approach or a combination thereof.]

[Public domain refers, for the purposes of this instrument, to intangible materials that, by their nature, are not or may not be protected by established intellectual property rights or related forms of protection by the legislation in the country where the use of such material is carried out. This could, for example, be the case where the subject matter in question does not fill the prerequisite for intellectual property protection at the national level or, as the case may be, where the term of any previous protection has expired.]

[Publicly available means [subject matter]/[traditional knowledge] that has lost its distinctive association with any indigenous community and that as such has become generic or stock knowledge, notwithstanding that its historic origin may be known to the public.]
**Traditional knowledge** [refers to]/[includes]/[means], for the purposes of this instrument, know-how, skills, innovations, practices, teachings and learnings of [indigenous peoples] and [local communities]/[or a state or states].

[Traditional knowledge may be associated, in particular, with fields such as agriculture, the environment, healthcare and indigenous and traditional medical knowledge, biodiversity, traditional lifestyles and natural resources and genetic resources, and know-how of traditional architecture and construction technologies.]

[Unauthorized use is use of protected traditional knowledge without the permission of the right holder.]

[“Use”]/[“utilization”] means

(a) where the traditional knowledge is included in a product [or] where a product has been developed or obtained on the basis of traditional knowledge:

(i) the manufacturing, importing, offering for sale, selling, stocking or using the product beyond the traditional context; or

(ii) being in possession of the product for the purposes of offering it for sale, selling it or using it beyond the traditional context.

(b) where the traditional knowledge is included in a process [or] where a process has been developed or obtained on the basis of traditional knowledge:

(i) making use of the process beyond the traditional context; or

(ii) carrying out the acts referred to under sub-clause (a) with respect to a product that is a direct result of the use of the process;
(c) the use of traditional knowledge in non-commercial research and development; or

(d) the use of traditional knowledge in commercial research and development.

ARTICLE 1

SUBJECT MATTER OF [PROTECTION]/[INSTRUMENT]

The subject matter of [protection]/[this instrument] is traditional knowledge:

(a) that is created, and [maintained] in a collective context, by indigenous [peoples] and local communities [or nations] [,whether it is widely spread or not];

(b) that is [directly] [linked]/[distinctively associated] with the cultural [and]/[or] social identity and cultural heritage of indigenous [peoples] and local communities [or nations];

(c) that is transmitted from generation to generation, whether consecutively or not;

(d) which may subsist in codified, oral or other forms; and [or]

(e) which may be dynamic and evolving.

[Criteria for Eligibility

Protected traditional knowledge is traditional knowledge that is [distinctively] associated with the cultural heritage of beneficiaries as defined in Article 2, that is generated, [maintained], shared and transmitted in a collective context, is intergenerational and has been used for a term as has been determined by each [Member State]/[Contracting Party] [but not less than 50 years].]
ARTICLE 2

BENEFICIARIES OF PROTECTION

2.1 Beneficiaries of protection are indigenous peoples and local communities who create, hold, maintain, use and/or develop the subject matter/traditional knowledge meeting the criteria for eligibility defined in Article 1/3.

Alternative

2.1 Beneficiaries of protection are indigenous peoples and local communities who create, hold, maintain, use and/or develop the subject matter/traditional knowledge defined in Article 1.

[End of alternative]

2.2 Where the subject matter/traditional knowledge is not claimed by specific indigenous peoples or local communities despite reasonable efforts to identify them, Member States/Contracting Parties may designate a national authority as custodian of the benefits/beneficiaries of protection under this instrument where the subject matter/traditional knowledge meeting the eligibility criteria in Article 1 as defined in Article 1:

(a) is held by a community whose in a territory is that is entirely and exclusively coterminous with the territory of that Member State/Contracting Party;

836 Where a Member State’s/Contracting Party’s constitution does not recognize indigenous or local communities, then that Member State/Contracting Party may act as a beneficiary with regard to the traditional knowledge that exists within its territory. [Note: This footnote is to be read as part of the alternative to Paragraph 1.]
(b) is not confined to a specific indigenous [people] or local community;

(c) is not attributable to a specific indigenous [people] or local community; or

(d) is not claimed by a specific indigenous [people] or local community.]

2.3 [The [identity] of any national authority established under Paragraph 2 [should]/[shall] be communicated to the International Bureau of the World Intellectual Property Organization.]

ARTICLE 3

[[CRITERIA FOR AND] SCOPE OF PROTECTION

Scope of Protection

3.1 Where the [subject matter]/[traditional knowledge]/[protected traditional knowledge] is [sacred], [secret] or [otherwise known] [closely held] within indigenous [peoples] or local communities, [Member States]/[Contracting Parties] [should]/[shall]:

(a) [ensure that beneficiaries have the exclusive and collective right to]/[provide legal, policy and administrative measures, as appropriate and in accordance with national law that allow beneficiaries to]:

i. [create,] maintain, control and develop said [subject matter]/[traditional knowledge]/[protected traditional knowledge];
ii. discourage the unauthorized disclosure, use or other uses of [secret] [protected] traditional knowledge;

iii. [authorize or deny the access to and use/utilization of said [subject matter]/[traditional knowledge]/[protected traditional knowledge] based on prior and informed consent; and]

iv. [be informed of access to their traditional knowledge through a disclosure mechanism in intellectual property applications, which may [shall] require evidence of compliance with prior informed consent or approval and involvement and benefit sharing requirements, in accordance with national law and international legal obligations],

(b) [ensure that]/[encourage] users [to]:

i. attribute said [subject matter]/[traditional knowledge]/[protected traditional knowledge] to the beneficiaries;

ii. [provide beneficiaries with [a fair and equitable share of benefits]/[fair and equitable compensation], arising from the use/utilization of said [subject matter]/[traditional knowledge] based on mutually agreed terms;]

Alternative

ii. enter into an agreement with the beneficiaries to establish terms of use of the [subject matter]/[traditional knowledge]/[protected traditional knowledge];

[End of alternative]

iii. use/utilize the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the [subject matter]/[traditional knowledge]/[protected traditional knowledge].
3.2 Where the [subject matter]/[traditional knowledge]/[protected traditional knowledge] is still [held], [maintained], used [and]/[or] developed by indigenous [peoples] or local communities, and is publicly available [but neither widely known, [sacred], nor [secret]], [Member States]/[Contracting Parties] [should]/[shall] [ensure that]/[encourage] that users/[provide legal, policy and administrative measures, as appropriate and in accordance with national law to [ensure] [encourage] users [to]]:

(a) attribute and acknowledge the beneficiaries as the source of the [subject matter]/[traditional knowledge]/[protected traditional knowledge, unless the beneficiaries decide otherwise, or the [subject matter]/[traditional knowledge] is not attributable to a specific indigenous [people] or local community;

(b) [provide the beneficiaries with [a fair and equitable share of benefits]/[fair and equitable compensation] arising from the use/utilization of said [subject matter]/[traditional knowledge]/[protected traditional knowledge] based on mutually agreed terms;]

Alternative

(b) enter into an agreement with the beneficiaries to establish terms of use of the [subject matter]/[traditional knowledge]/[protected traditional knowledge];

[End of alternative]

(c) [use/utilize the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the [subject matter]/[traditional knowledge]/
[protected traditional knowledge][; and][.]

(d) be informed of access to their traditional knowledge through a disclosure mechanism in intellectual property applications, which may [shall] require evidence of compliance with prior informed consent or approval and involvement and benefit sharing requirements, in accordance with national law and international legal obligations.

3.3 Where the [subject matter]/[traditional knowledge]/[protected traditional knowledge] is [publicly available, widely known [and in the public domain]] [not covered under Paragraphs 2 or 3], and protected under national law, [Member States]/[Contracting Parties] [should]/[shall] [ensure that]/[encourage] users of said [subject matter]/[traditional knowledge] [to]:

(a) attribute said [subject matter]/[traditional knowledge]/[protected traditional knowledge] to the beneficiaries;

(b) use/utilize the knowledge in a manner that respects the cultural norms and practices of the beneficiary as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the [subject matter]/[traditional knowledge]/[protected traditional knowledge][;] [and]

(c) where applicable, deposit any user fee into the fund constituted by such [Member State]/[Contracting Party].]

Alternative

3.3 Protection does not extend to traditional knowledge that is widely known or used outside the community of the beneficiaries as defined in Article 2.1, [for a reasonable period of time], in the public domain, protected by an intellectual property right or the application of
principles, rules, skills, know-how, practices, and learning normally and generally well-known.]

[ARTICLE 3 BIS

COMPLEMENTARY MEASURES

3BIS.1 [Member States]/[Contracting Parties] should [endeavour to], subject to and consistent with national and customary law:

(a) facilitate/encourage the development national traditional knowledge databases for the defensive protection of traditional knowledge, [including through the prevention of the erroneous grant of patents], and/or for transparency, certainty, conservation purposes and/or transboundary cooperation;

(b) [facilitate/encourage, as appropriate, the creation, exchange and dissemination of, and access to, databases of genetic resources and traditional knowledge associated with genetic resources;]

(c) [provide opposition measures that will allow third parties to dispute the validity of a patent [by submitting prior art];]

(d) encourage the development and use of voluntary codes of conduct;

(e) [discourage information lawfully within the beneficiaries’ control from being disclosed, acquired by or used by others without the beneficiaries’ [consent], in a manner contrary to fair commercial practices, so long as it is [secret], that reasonable steps have been taken to prevent unauthorized disclosure, and has value;]

(f) [consider the establishment of databases of traditional knowledge that are accessible to patent offices to avoid the erroneous grant of patents compile and maintain such databases in accordance with national law;]
i. there should be minimum standards to harmonize the structure and content of such databases;

ii. the content of the databases should be:

   a. languages that can be understood by patent examiners;

   b. written and oral information regarding traditional knowledge;

   c. relevant written and oral prior art related to traditional knowledge.

(g) [develop appropriate and adequate guidelines for the purpose of conducting search and examination of patent applications relating to traditional knowledge by patent offices;]

3BIS.2 [In order to document how and where traditional knowledge is practiced, and to preserve and maintain such knowledge, efforts [should]/[shall] be made by national authorities to codify the oral information related to traditional knowledge and to develop databases of traditional knowledge.]

3BIS.3 [Member States]/[Contracting Parties] [should]/[shall] consider cooperating in the creation of such databases, especially where traditional knowledge is not uniquely held within the boundaries of a [Member States]/[Contracting Parties]. If protected traditional knowledge pursuant to article 1.2 is included in a database, the protected traditional knowledge should only be made available to others with the prior informed consent or approval and involvement of the traditional knowledge holder.
3BIS.4 Efforts[should]/[shall] also be made to facilitate access to such databases by intellectual property offices, so that the appropriate decision can be made. To facilitate such access, [Member States]/[Contracting Parties] [should]/[shall] consider efficiencies that can be gained from international cooperation. The information made available to intellectual property offices [should]/[shall] only include information that can be used to refuse a grant of cooperation, and thus [should]/[shall] not include protected traditional knowledge.

3BIS.5 Efforts [should]/[shall] be made by national authorities to codify the information related to traditional knowledge for the purpose of enhancing the development of databases of traditional knowledge, so as to preserve and maintain such knowledge.

3BIS.6 Efforts [should]/[shall] also be made to facilitate access to information including information made available in databases relating to traditional knowledge by intellectual property offices.

3BIS.7 Intellectual property offices [should]/[shall] ensure that such information is maintained in confidence, except where the information is cited as prior art during the examination of a patent application.]
ARTICLE 4
SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS/APPLICATION

4.1 [Member States [should]/[shall] ensure that [accessible, appropriate and adequate] 
criminal, civil [and] or administrative] enforcement procedures[, dispute resolution 
mechanisms][, border measures][, sanctions] [and remedies] are available under their laws 
against the [willful or negligent [harm to the economic and/or moral interest]] [infringement of 
the protection provided to traditional knowledge under this instrument] [[misappropriation/
misuse/unauthorized use/unfair and inequitable uses] or misuse of traditional knowledge] 
sufficient to constitute a deterrent to further infringements.]

4.2 The procedures referred to in Paragraph 1 should be accessible, effective, fair, equitable, 
adequate [appropriate] and not burdensome for [holders]/[owners] of protected traditional 
knowledge. [These procedures should also provide safeguards for legitimate third party interests and the public interest.]

4.3 [The beneficiaries [should]/[shall] have the right to initiate legal proceedings where their 
rights under Paragraphs 1 and 2 are violated or not complied with.]

4.4 [Where appropriate, sanctions and remedies should reflect the sanctions and remedies 
that indigenous people and local communities would use.]

4.5 [Where a dispute arises between beneficiaries or between beneficiaries and users of 
traditional knowledge, each party [may]/[shall be entitled to] refer the issue to an [independent] 
alternative dispute resolution mechanism recognized by international, regional or [, if both 
parties are from the same country, by] national law [, and that is most suited to the holders of 
traditional knowledge].]
4.6 [Where, under applicable domestic law, the [intentional] wide diffusion of [protected subject matter]/[traditional knowledge] beyond a recognizable community of practice has been determined to be the result of an act of [misappropriation/misuse/unauthorized use/unfair and inequitable uses] or other violation of national law, the beneficiaries shall be entitled to fair and equitable compensation/royalties.]

[ARTICLE 4 BIS

DISCLOSURE REQUIREMENT

4 BIS.1 [[Patent and plant variety] Intellectual property applications that concern [an invention] any process or product that relates to or uses traditional knowledge shall include information on the country from which the [inventor or the breeder] applicant collected or received the knowledge (the providing country), and the country of origin if the providing country is not the same as the country of origin of the traditional knowledge. The application shall also state whether prior informed consent or approval and involvement to access and use has been obtained.]

4 BIS.2 [If the information set out in Paragraph 1 is not known to the applicant, the applicant shall state the immediate source from which the [inventor or the breeder] applicant collected or received the traditional knowledge.]

4 BIS.3 [If the applicant does not comply with the provisions in Paragraphs 1 and 2, the application shall not be processed until the requirements are met. The [patent or plant variety] intellectual property office may set a time limit for the applicant to comply with the provisions]
in paragraphs 1 and 2. If the applicant does not submit such information within the set time limit, the [patent or plant variety] intellectual property office may reject the application.]

4 BIS.4 [Rights arising from a granted patent or a granted plant variety right shall not be affected by [any later discovery of] a failure by the applicant to comply with the provisions in Paragraphs 1 and 2. Other sanctions, outside of the patent system and the plant variety system, provided for in national law, including criminal sanctions such as fines, may however be imposed.]

Alternative

4 BIS.4 [Rights arising from a grant shall be revoked and rendered unenforceable when the applicant has failed to comply with the obligations of mandatory requirements as provided for in this article or provided false or fraudulent information.]

[End of alternative]

Alternative

[NO DISCLOSURE REQUIREMENT

Patent disclosure requirements shall not include a mandatory disclosure requirement relating to traditional knowledge unless such disclosure is material to the patentability criteria of novelty, inventive step or enablement.]
ARTICLE 5

ADMINISTRATION [OF RIGHTS]/[OF INTERESTS]

5.1 [Member States]/[Contracting Parties] [may]/[shall] [establish]/[appoint] a competent authority or authorities, [with the free, prior and informed consent of] [in consultation with] [traditional knowledge [holders]/[owners]], in accordance with their national law [and without prejudice to the right of traditional knowledge [holders]/[owners] to administer their rights/interests according to their customary protocols, understandings, laws and practices].

Optional addition

[Where so requested by the beneficiaries, a competent authority may, to the extent authorized by the beneficiaries and for their direct benefit, assist with the management of the beneficiaries’ rights/interests under this [instrument].]

[End of optional addition]

Alternative

5.1 [Member States]/[Contracting Parties] may establish a competent authority, in accordance with national law, to administer the rights/interests provided for by this [instrument].

[End of alternative]

5.2 [The [identity] of any authority established under Paragraph 1 [should]/[shall] be communicated to the International Bureau of the World Intellectual Property Organization.]
[ARTICLE 6

EXCEPTIONS AND LIMITATIONS

General Exceptions

6.1 [Member States]/[Contracting Parties] may adopt appropriate limitations and exceptions under national law [with the prior informed consent or approval and involvement of the beneficiaries] [in consultation with the beneficiaries] [with the involvement of beneficiaries][, provided that the use of [protected] traditional knowledge:

(a) [acknowledges the beneficiaries, where possible;]

(b) [is not offensive or derogatory to the beneficiaries;]

(c) [is compatible with fair practice;]

(d) [does not conflict with the normal utilization of the traditional knowledge by the beneficiaries; and]

(e) [does not unreasonably prejudice the legitimate interests of the beneficiaries taking account of the legitimate interests of third parties.]]

6.2 [When there is reasonable apprehension of irreparable harm related to [sacred] and [secret] traditional knowledge, [Member States]/[Contracting Parties] [may]/[shall]/[should] not establish exceptions and limitations.]

Specific Exceptions

6.3 [[In addition to the limitations and exceptions provided for under Paragraph 1,] [Member States]/[Contracting Parties] may adopt appropriate limitations or exceptions, in accordance with national law, for the following purposes:

(a) teaching, learning, but not research resulting in profit-marking or commercial purposes;]
(b) for preservation, display, research and presentation in archives, libraries, museums or cultural institutions, for non-commercial cultural heritage or other purposes in the public interest; and

(c) in the case of a national emergency or other circumstances of extreme urgency [or in cases of public non-commercial use];

(d) [the creation of an original work of authorship inspired by traditional knowledge.]

This provision, with the exception of Subparagraph (c), [should]/[shall] not apply to traditional knowledge described in Article 3.1.

6.3 Regardless of whether such acts are already permitted under Paragraph 1, the following shall be permitted:

(a) the use of traditional knowledge in cultural institutions recognized under the appropriate national law, archives, libraries, museums for non-commercial cultural heritage or other purposes in the public interest, including for preservation, display, research and presentation should be permitted; and

(b) the creation of an original work of authorship inspired by traditional knowledge.

6.4 [[There shall be no right to [exclude others] from using knowledge that:]][The provisions of Article 3 shall not apply to any use of knowledge that:]

(a) has been independently created [outside the beneficiaries’ community];

(b) [legally] derived from sources other than the beneficiary; or

(c) is known [through lawful means] outside of the beneficiaries’ community.]
6.5 [Protected traditional knowledge shall not be deemed to have been misappropriated or
misused if the protected traditional knowledge was:

(a) obtained from a printed publication;

(b) obtained from one or more holders of the protected traditional knowledge with their
prior informed consent or approval and involvement; or

(c) mutually agreed terms for [access and benefit sharing]/[fair and equitable
compensation] apply to the protected traditional knowledge that was obtained, and
were agreed upon by the national contact point.]

6.6 [[Member States]/[Contracting Parties] may exclude from protection diagnostic,
therapeutic and surgical methods for the treatment of humans or animals.]

6.7 [National authorities shall exclude from protection traditional knowledge that is already
available without restriction to the general public.]
ARTICLE 7

TERM OF PROTECTION/RIGHTS

[Member States]/[Contracting Parties] may determine the appropriate term of protection/rights of traditional knowledge in accordance with [Article 3/[[which may] [should]/[shall] last as long as the traditional knowledge fulfills/satisfies the [criteria of eligibility for protection] according to Article [1]/[3]].]

ARTICLE 8

FORMALITIES

Option 1

8.1 [Member States]/[Contracting Parties] [should]/[shall] not subject the protection of traditional knowledge to any formality.

Option 2

8.1 [[Member States]/[Contracting Parties] [may] require formalities for the protection of traditional knowledge.]

Alternative

[The protection of traditional knowledge under Article 3.1 [should]/[shall] not be subject to any formality. However, in the interest of transparency, certainty and the conservation of traditional knowledge, the relevant national authority (or authorities) or intergovernmental regional authority (or authorities) may maintain registers or other records of traditional knowledge to facilitate protection under Articles 3.2 and 3.3.]

[End of alternative]
ARTICLE 9

TRANSITIONAL MEASURES

9.1 These provisions [should]/[shall] apply to all traditional knowledge which, at the moment of the provisions coming into force, fulfills the criteria set out in Article [1]/[3].

Optional addition

9.2 [[Member States]/[Contracting Parties] [should]/[shall] ensure [the necessary measures to secure] the rights [acknowledged by national law] already acquired by third parties are not affected, in accordance with its national law and its international legal obligations.]

Alternative

9.2 [[Member States]/[Contracting Parties] [should]/[shall] provide that continuing acts in respect of traditional knowledge that had commenced prior to the coming into force of this [instrument] and which would not be permitted or which would be otherwise regulated by this [instrument], [should be brought into conformity with these provisions within a reasonable period of time after its entry into force[, subject to respect for rights previously acquired by third parties in good faith]/should be allowed to continue].

Alternative

9.2 [Notwithstanding Paragraph 1, [Member States]/[Contracting Parties] [should]/[shall] provide that:

(a) anyone who, before the date of entry into force of this instrument, has commenced utilization of traditional knowledge which was legally accessed, may continue such utilization of the traditional knowledge[, subject to a right of compensation];

(b) such right of utilization shall also, on similar conditions, be enjoyed by anyone who has made substantial preparations to utilize the traditional knowledge.
(c) the foregoing gives no right to utilize traditional knowledge in a way that contravenes the terms the beneficiary may have set out as a condition for access.]

[ARTICLE 10

RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument [should]/[shall] establish a mutually supportive relationship [between [intellectual property [patent] rights [directly based on] [involving] [the utilization of] traditional knowledge and with relevant [existing] international agreements and treaties.]

[ARTICLE 11

NATIONAL TREATMENT

[The rights and benefits arising from the protection of traditional knowledge under national/domestic measures or laws that give effect to these international provisions [should]/[shall] be available to all eligible beneficiaries who are nationals or residents of a [Member State]/[Contracting Party] [prescribed country] as defined by international obligations or undertakings. Eligible foreign beneficiaries [should]/[shall] enjoy the same rights and benefits as enjoyed by beneficiaries who are nationals of the country of protection, as well as the rights and benefits specifically granted by these international provisions.]

Alternative
[Nationals of a [Member State]/[Contracting Party] may only expect protection equivalent to that contemplated in this instrument in the territory of another [Member State]/[Contracting Party] even where that other [Member State]/[Contracting Party] provides for more extensive protection for their nationals.]

[End of alternative]

**Alternative**

[Each [Member State]/[Contracting Party] [should]/[shall] in respect of traditional knowledge that fulfills the criteria set out in Article 1, accord within its territory to beneficiaries of protection as defined in Article 2, whose members primarily are nationals of or are domiciled in the territory of, any of the other [Member States]/[Contracting Parties], the same treatment that it accords to its national beneficiaries.]

[End of alternative]
ARTICLE 12

TRANSBOUNDARY COOPERATION

12.1 In instances where the same [protected] traditional knowledge [under Article 3] is found within the territory of more than one [Member State]/[Contracting Party], those [Member States]/[Contracting Parties] [should]/[shall] endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this [instrument].

12.2 Where the same [protected] traditional knowledge [under Article 3] is shared by one or more indigenous and local communities in several [Member States]/[Contracting Parties], those [Member States]/[Contracting Parties] [should]/[shall] endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objectives of this [instrument].

[End of Annex and of Document]