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INTELLECTUAL PROPERTY AND BIOPROSPECTING: A MODEL LEGAL FRAMEWORK

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Society has long enjoyed the benefits of medical advances. In numerous cases, the biotechnology and pharmaceutical (biopharmaceutical) industries build on knowledge accumulated over centuries by traditional communities. As in the case of aspirin and morphine, the use of this knowledge has reduced the time and cost it takes to develop new drugs. Despite the community's contribution, the law only provides rights 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 forefront, and this creates tension between source communities and pharmaceutical companies. The controversy surrounding the involvement of Pfizer and Unilever in research into weight loss products based on the Hoodia plant used by the San people of the Kalahari Desert for centuries as an appetite suppressant is a prime example of potential problems with the current system.[1] The tension that arises in this relationship is whether source communities have any claim emanating from their input in the modern drug development process.

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[1] ABENA DOVE OSSEO-ASARE, BITTER ROOTS: THE SEARCH FOR HEALING PLANTS IN AFRICA (2014).

This article asks whether legal intervention is necessary to regulate the relationship between the knowledge-holder communities and users of traditional knowledge ("TK")—the know-how, skills, innovations, and practices of indigenous people and local communities. Answering in the affirmative, this article then addresses the question of what form of legal protection is justified. After describing the key problem and situating TK within the public goods literature in the first part, the second part of the article examines four of the major channels through which the production of knowledge goods is supported. These include public investment, private investment, secrecy and group cooperation. Because these channels have their own advantages and disadvantages, the article argues that a combination of these frameworks is needed to respond to the diverse interests of the multiple stakeholders involved. These alternative frameworks should consider the full spectrum from a simple right of attribution to a 'communal right' requiring prior consent before TK is accessed. Part three then proceeds to outline the nature and scope of a 'communal bioprospecting right' for source communities. The bioprospecting right would be based on the disclosure of TK in a publicly accessible or restricted database. The article concludes by outlining what the nature and scope of TK codification should be and considers some of the implications that flow from the proposed model legal framework.

I. INTRODUCTION

Biopharmaceutical firms involved in bioprospecting, which is the process of using plant and animal species to develop new drugs, often use the knowledge of indigenous people and local communities[2] to make the process more efficient. The input that indigenous people and local communities provide to biopharmaceutical firms is beneficial in reducing the time and cost involved in modern drug development, at least in the initial stages of the process. If a successful drug is developed, the inventors of the drug are rewarded through patent rights that give the inventor a right

[2] While the term "indigenous peoples" is used in the literature to refer generally to native populations who live with settler communities, the term "local communities" is used in reference to communities that reside in countries from which colonizing powers have left, but in which the community continues to be secluded from the mainstream society in that country.

to exclude others from making and using the protected invention.[3] The knowledge that indigenous peoples and local communities developed over generations is considered to be part of the "public domain" free of encumbrances. There is no legal requirement or business practice in which attribution is given or benefits flow back to the source communities. In response to this status quo, source communities and governments of countries in which a significant indigenous population resides are increasingly taking a protectionist stance. The governments of Brazil, India, and China, for example, have enacted laws restricting access to the genetic resources and traditional knowledge within their borders.[4] This creates a potential risk in which the bioprospecting relationships cannot be sustained in the long term. Biopharmaceutical firms involved in these relationships face public relations crises when they are accused of engaging in unfair practices. While some accusations may be justified, some firms face these allegations because of the lack of clarity in legal frameworks or the expectation of interested shareholders. Compounding this problem, TK and genetic resources on which it relies face an alarming rate of loss. Since the early 1990s, there have been several domestic and global initiatives attempting to encourage the conservation of biodiversity and traditional knowledge.[5]

A previous publication[6] has outlined these two problems and examined the rationale for legal intervention. The publication

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[3] 35 U.S.C. § 154 (2012) (noting that patent rights in the US grant the patentee of a product the right to make, use, sell, offer for sale, and import the patented product).

[4] Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 757–76 (Keith E. Maskus & Jerome Reichman eds., 2005) (outlining national legislations enacted to protect TK in India, Brazil, Peru, the Philippines, and the Africa model legislation).

[5] Charles McManis, *Biodiversity, Biotechnology and Traditional Knowledge Protection: Law, Science and Practice*, *in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE 5 (2007).

[6] Aman Gebru, *International Intellectual Property Law and the Protection of Traditional Knowledge: From Cultural Conservation to Knowledge Codification*, 15 ASPER REV. INT'L BUS. TRADE L. 293 (2015).

concludes by noting that the codification and disclosure of TK should be a key rationale for legal intervention. This article builds on the discussion by outlining a model legal framework based on property rights that balances the interests of source communities and has the potential to facilitate bioprospecting partnerships. Part I starts with the Hoodia story to help introduce the issues that might arise in bioprospecting projects. It summarizes research showing the value of TK and the alarming rate at which the knowledge is disappearing. The section concludes by situating TK within the public goods literature and describing the problem from a welfare economics perspective. Part II outlines four major alternative channels that support the production of knowledge goods and examines the potential and limitation of each channel to encourage investments in TK. It analyzes the advantages and disadvantages of government provision, private rights, secrecy, and group cooperation in encouraging source communities to invest in codifying their knowledge and disclosing it to outsiders. Because of the diverse worldviews and interests among stakeholders, the article advocates for the combination of these frameworks to govern bioprospecting relationships.

Since the recognition of private rights plays such a major role in the governance of modern knowledge, Part III of the article outlines a detailed model legal framework based on a "communal bioprospecting right." The purpose of granting the bioprospecting right is to address the key "tragedies" outlined in the article—the TK loss and the rising protectionist trend. The right can be expected to encourage investments in the codification and disclosure of TK thereby saving the knowledge from loss. This "incentive to codify"[7] rationale has two sides: the supply side and the 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.

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[7] *Id*.

The right would arise out of two types of databases in which source communities codify their TK: a publicly accessible database and a restricted database. A publicly accessible database would give source communities one of two alternative rights: an exclusive bioprospecting right or a right to share profits arising out of the use of their TK. A restricted database, the contents of which are kept confidential, would give source communities a right against unauthorized access. Part III concludes by proposing factors that should be considered in setting the breadth and term of the bioprospecting right. Parts IV to VI examine the nature and scope of TK codification and its implications for the different stakeholders involved. The article suggests the adoption of a holistic codification reflecting the availability of resources which will increase the value of codified TK for both the firms and source communities.

A. *The Hoodia Story*[8]

The San people, a community featured in the 1984 hit film "The Gods Must Be Crazy," are a group of hunter communities around the Kalahari Desert in southern Africa.[9] The San people chew on parts of the Hoodia plant to help them suppress their appetite when they go on long hunting trips.[10] While the San people and other neighboring communities have been using the Hoodia plant as an appetite suppressant for at least a couple hundred years, its use was not studied scientifically in detail until the 1980s when the Center for Scientific and Industrial Research (CSIR), an agency of the South African government, began a project to study the plant.[11] After decades of study and several trials, the center was able to isolate the active ingredient responsible for appetite suppression and named the compound P57.[12] In 1995, CSIR was granted its first patent in South Africa for the appetite suppressant qualities of the active elements

[8] For a detailed discussion of five of the most famous cases of the use of traditional medicinal knowledge in modern drug discovery, including the use of the Hoodia plant, see generally OSSEO-ASARE, *supra* note 1.

[9] *Id*. at 167.

[10] *Id*.

[11] *See id*. at 168, 170.

[12] *See id*. at 187–88.

extracted from the Hoodia plant.[13] Patent grants from other jurisdictions soon followed, including in the US and EU.[14] In exchange for payment, CSIR entered into licensing agreements with private companies including Phytopharm, Pfizer, and Unilever.[15] These firms invested millions of dollars in research and development for a weight loss product from the Hoodia extract.[16]

When the public heard news of the Hoodia extract patent, activists, academics, and non-governmental organizations began advocating for the sharing of profits related to P57 with the San people. In response, the South African San Council and the Working Group of Indigenous Minorities in South Africa (WIMSA) established a jointly managed trust where some funds from the sale of Hoodia plant would be deposited.[17] WIMSA thereafter brought legal action against CSIR, and, in a settlement agreement, CSIR agreed to pay 8% of milestone payments and 6% of the royalty payments from P57 into the trust.[18] In May 2005, CSIR paid R560,000 South African Rand into the trust, which they planned to spend on education and other projects that would create jobs for the San people.[19]

While the San people were hoping to share profits from P57, the marketing process hit a roadblock.[20] Producing a marketable product from the Hoodia extract proved much more challenging than anticipated.[21] Pfizer terminated its license in 2003 because of the

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[13] Rachel Wynberg, *Case Study 7: Access and Benefit-Sharing Agreements in the Commercial Development of Hoodia*, *in* CBD TECHNICAL SERIES NO. 38: ACCESS AND BENEFIT-SHARING IN PRACTICE: TRENDS IN PARTNERSHIPS ACROSS SECTORS 83, https://www.cbd.int/doc/publications/cbd-ts-38-en.pdf; *see also* South African Patent No. 983170.

[14] WIPO, *CASE STUDY: HOODIA PLANT (2008)*, http://www.wipo.int/export/sites/www/academy/en/about/global_network/educational_materials/cs1_hoodia.pdf; *see also* Int'l Patents Nos. US6376657, GB2338235, and WO9846243

[15] WIPO, *supra* note 14, at 2–3.

[16] *See* OSSEO-ASARE, *supra* note 1, at 189; WIPO, *supra* note 14, at 2.

[17] OSSEO-ASARE, *supra* note 1, at 191.

[18] OSSEO-ASARE, *supra* note 1, at 192; WIPO, *supra* note 14.

[19] OSSEO-ASARE, *supra* note 1, at 192. In current currency exchange, R560,000 South African rand would be approximately $ 42,218 USD.

[20] *See* OSSEO-ASARE, *supra* note 1, at 189.

[21] *See id.* at 189–90.

challenges and high cost associated with synthesizing and extracting P57.[22] In 2008, Unilever ended its license because of adverse side effects of the compound.[23] CSIR, however, continues to conduct research on the Hoodia plant, and now Hoodia-based products have become ubiquitous in the dietary supplement market.[24]

The Hoodia story shows the relationship between the various stakeholders in the use of TK, the complexities of using this knowledge in the drug discovery process, and potential solutions. Before analyzing these issues, however, it seems necessary to first define the term "traditional knowledge."

B. *Defining Traditional Knowledge*[25]

Scholars have yet to agree on a universally accepted definition of TK.[26] However, there is sizable literature on its value, protection, and conservation.[27] The term traditional knowledge is given narrow

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[22] Wynberg, *supra* note 13, at 83.

[23] OSSEO-ASARE, *supra* note 1, at 189.

[24] WIPO, *supra* note 14.

[25] Although defining the key and complex terms in this paper is necessary to provide a coherent and detailed analysis, it should be noted that the practice of defining terms such as "traditional knowledge," "indigenous peoples," and "local communities" is highly controversial. Some indigenous peoples and local communities find the process of defining these terms as part of a bigger problem of disempowerment, especially when the definition dissects concepts and values they consider to be holistic. *See* WIPO, INTERGOVERNMENTAL COMM. ON INTELL. PROP. AND GENETIC RES., TRADITIONAL KNOWLEDGE AND FOLKLORE, WIPO/GRTKF/IC/17/INF/9, LIST AND BRIEF TECHNICAL EXPLANATION OF VARIOUS FORMS IN WHICH TRADITIONAL KNOWLEDGE MAY BE FOUND (2010), http://www.wipo.int/edocs/mdocs/sct/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_9.pdf; *see also* Maeli Astruc, *Indigenous Peoples Present Their Perspectives on Traditional Knowledge at WIPO*, INTELL. PROP. WATCH (Mar. 25, 2014), https://www.ip-watch.org/2014/03/25/indigenous-peoples-present-their-perspectives-on-traditional-knowledge-at-wipo/.

[26] *See generally* INTERGOVERNMENTAL COMM. ON INTELLECTUAL PROP. & GENETIC RES. TRADITIONAL KNOWLEDGE AND FOLKLORE, WIPO/GRTKF/IC/4/8 *ELEMENTS OF A SUI GENERIS SYSTEM OF PROTECTION OF TRADITIONAL KNOWLEDGE,* (2002).

[27] *See generally* PETER DRAHOS & SUSY FRANKEL, INDIGENOUS PEOPLE'S INNOVATION: INTELLECTUAL PROPERTY PATHWAYS TO DEVELOPMENT (2012); CHIDI OGUAMANAM, INTERNATIONAL LAW AND INDIGENOUS KNOWLEDGE:

(*sensu stricto*) and broad (*sensu lato*) scopes in the relevant literature.[28] In its narrow sense, the term refers to the know-how, skills, innovations, and practices of indigenous peoples and local communities.[29] The broader definition of the term includes traditional "know-how," but it also extends to cultural expressions such as folklore, music, dances, and artistic creations.[30] This article adopts the narrower version of the term because a narrow definition allows for a detailed and coherent analysis and because it is the most frequently used definition in literature.[31] Therefore, for the purposes of this article, the term TK refers to the know-how, skills, practices, innovations, and learnings of indigenous peoples and local communities. It should be stressed, however, that the definition of the term TK is highly contentious, with multiple approaches being adopted by source communities and scholars working in the field.[32] It must be noted at the outset that the term "traditional" is not used to connote its antiquity.[33] Instead, "traditional" refers to the way the knowledge is developed, used, and shared.[34] While modern

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INTELLECTUAL PROPERTY, PLANT BIODIVERSITY, AND TRADITIONAL MEDICINE (2006).

[28] *See* OGUAMANAM, *supra* note 27, at 21.

[29] WIPO, INTERGOVERNMENTAL COMM. ON INTELL. PROP. AND GENETIC RES., TRADITIONAL KNOWLEDGE AND FOLKLORE, WIPO/GRTKF/IC/3/9, TRADITIONAL KNOWLEDGE: OPERATIONAL TERMS AND DEFINITIONS, Annex III at 5, http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/wipo_grtkf_ic_3_9.pdf.

[30] *Id*.

[31] Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (Keith E. Maskus & Jerome H. Reichman eds., 2005).

[32] For a list of definitions adopted by scholars, see WIPO, *supra* note 25.

[33] Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office: A Road Under Construction*, *in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE 244 (2007).

[34] *See* Antony Taubman, *Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 521, 524 (Jerome Reichman & Keith E. Maskus eds., 2005).

knowledge uses evidence-based investigation, TK is characterized by trial-and-error methodologies and intuition.[35]

A variety of adjectives are frequently appended to "knowledge" in this context, including "indigenous," "traditional," "native/aboriginal," "local," and "informal."[36] The term "indigenous people" refers to people (including their descendants) who were colonized by European powers in countries where the colonizing population remains the dominant group.[37] While some scholars limit their definition only to the knowledge of indigenous peoples, others argue that the term should be expanded to include local communities. For instance, Chidi Oguamanam argues that because of the many similarities between the knowledge that indigenous peoples and local communities hold, the term should include knowledge held by communities in Africa and Asia that have seen the withdrawal of colonial powers.[38] In this sense, TK would refer to the know-how, skills, practices, and innovations of "indigenous peoples . . . and . . . to members of the so-called local communities or non-Western cultures, be they indigenous in the strict sense or not."[39]

"Indigenous knowledge" and "knowledge of local communities" share common features relevant for the discussions in this article, and, therefore, in this article, the term TK is used to refer to the know-how, skills, practices, and innovations of both

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[35] The trial-and-error approach, as opposed to a formalistic and technical approach, is one in which the traditional knowledge or wisdom is slowly developed through the experiences of generations of community members. Although each community has its own way of building on the knowledge that is passed down from elders, some of the common mechanisms include through stories and songs that communicate the ways in which resources in the surrounding environment could be used for food, health needs, shelter, navigation etc. *See* Carvalho, *supra* note 33, at 244 (listing the four elements of TK including the fact that it based on "trial-and-error" approach); Reichman, *supra* note 31, at 356.

[36] OGUAMANAM, *supra* note 27.

[37] Stephen R. Munzer & Kal Raustiala, *The Uneasy Case for Intellectual Property Rights in Traditional Knowledge*, 27 CARDOZO ARTS ENTERTAIN. L.J. 37, 48 n.25 (2009).

[38] OGUAMANAM, *supra* note 27, at 22.

[39] *Id.* at 20–26.

indigenous peoples and local communities. Thus, the focus is on the isolation of communities from mainstream societies. The term "users," on the other hand, refers to diverse groups of individuals or firms with differing backgrounds and interests (commercial or non-commercial) that use TK to further their goals.

In the face of this complex group of stakeholders, it is helpful to clarify the focus of this article. The literature on the protection of TK uses the term "protection" in two ways: defensive and positive. Defensive protection seeks to stop non-indigenous people from claiming intellectual property (IP) rights[40] over TK.[41] For instance, traditional medicinal knowledge (TMK) could be used to invalidate non-innovative patents through disclosure of the TMK to patent examiners.[42] Most attempts at defensive protection are not contentious as they seek to improve the existing IP system. The other mode of TK protection—positive protection—is more controversial, as it aims to provide knowledge-holding communities with the power to control how their knowledge is used by outsiders.[43] This article will focus on the positive mode of protection.

C. *The Value of Traditional Knowledge*

TK may be useful in two ways: first, as an independent body of knowledge that indigenous and local communities use, and second,

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[40] The term "intellectual property rights" here refers to the rights that are granted over scientific, literary, and artistic creations that are the subject matters of patents, copyrights and trademark rights.

[41] WIPO, INTERGOVERNMENTAL COMM. ON INTELL. PROP. AND GENETIC RES., TRADITIONAL KNOWLEDGE AND FOLKLORE, WIPO/GRTKF/IC/6/8, DEFENSIVE PROTECTION MEASURES RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE: AN UPDATE (2003), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_6/wipo_grtkf_ic_6_8.pdf.

[42] The Traditional Knowledge Digital Library, which has documented thousands of Indian TMK, has been used by patent offices around the world to invalidate non-innovative patents. *See* TRADITIONAL KNOWLEDGE DIGITAL LIBRARY ("TKDL"), http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng (last visited Oct. 29, 2017).

[43] VERA SHRIVASTAV, PROTECTION OF TRADITIONAL KNOWLEDGE WITHIN THE EXISTING FRAMEWORK OF INTELLECTUAL PROPERTY RIGHTS: DEFENSIVE AND POSITIVE APPROACH (July 7, 2014) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463017.

as an input for the production of goods and services in modern industries. This article is concerned with the use of TK as an input in modern industries. One of the best examples of this type of value is the use of TMK in the modern drug discovery process. Thus, TMK will be used as an example throughout this article.

Various sources have examined the role TMK plays in modern medicine. For instance, one study revealed that in the context of plant screenings, the use of TMK increased the chances of getting a preliminary hit[44] from 6% (without the use of TMK) to 25% (with the use of TMK).[45] This means that in the initial stages of research, scientists would have a considerably higher chance of selecting a compound with an active ingredient from a collection of plants. Other research has revealed the predictive role that TMK plays in drug discovery.[46] In one study, 80% of the drugs tested were used to treat the same ailments in both modern and traditional medicine.[47] These statistics, however, do not mean that 80% of drugs are *derived* from TMK. Although challenged by some, the value of TMK in modern drug discovery has repeatedly been demonstrated. The information provided through TMK would complement the scientific process at least in the sample selection stages. For instance, TMK has played a significant role in the attempt to find a cure for AIDS:

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[44] "Preliminary hit" is the compound that is selected from a large number of compounds because of either 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. *See* Benoit Deprez & Rebecca Deprez-Poulain, *Hit-to-Lead: Driving Forces for the Medicinal Chemist,* 4 CURR. TOP. MED. CHEM. i, i (2004); Rebecca Deprez-Poulain & Benoit Deprez, *Facts, Figures and Trends in Lead Generation*, 4 CURR. TOP. MED. CHEM. 569–80 (2004).

[45] Michael Balick, *Ethnobotany and the Identification of Therapeutic Agents from the Rainforest*, *in* BIOACTIVE COMPOUNDS FROM PLANTS 22, 28 (D. J. Chadwick & J. Marsh eds., 1990).

[46] *See* C. Haris Saslis-Lagoudakis et al., *Phylogenies Reveal Predictive Power of Traditional Medicine in Bioprospecting*, 109 PROC. NATL. ACAD. SCI. 15835–40 (2012).

[47] Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENVTL. HEALTH PERSP., 69, 71–72 (2001), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240543/.

> 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.[48]

The implication is that consulting a shaman increases the chances of a scientist producing a cure from 5.56% to 25%. Although much more research and development may be required to enhance TMK beyond its traditional use, the role TMK plays is crucial. Similarly, one can imagine that other types of TK, such as traditional agricultural knowledge ("TAK") and traditional environmental knowledge ("TEK"), would have significant value as input in modern research.

D. *The Tragedy of Traditional Knowledge*

Although TK holds considerable value, the body of knowledge is diminishing rapidly. Anthropologists and other researchers have been sounding the alarm on the distressing rate of TK loss. "For instance, research by Victoria Reyes-García 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).'[49] The researchers identified that TK loss is higher in communities living close to cities than those in remote villages."[50] The increasing urbanization of rural communities spurred by globalization can only be expected to increase the rate of TK loss. TMK especially seems

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[48] Daniel Goleman, *Shamans and Their Lore May Vanish with Forests*, N.Y. TIMES (June 11, 1991), http://www.nytimes.com/1991/06/11/science/shamans-and-their-lore-may-vanish-with-forests.html.

[49] Victoria Reyes-García et al., *Evidence of Traditional Knowledge Loss Among a Contemporary Indigenous Society*, 34 EVOL. HUM. BEHAV. 249, 249 (2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837211/.

[50] Aman Gebru, *The Global Protection of Traditional Knowledge: Searching for the Minimum Consensus*, 17 J. MARSHALL REV. INTELL. PROP. L. 42, 44-45 (2017); *id*. at 252.

to be facing a high rate of loss. Dr. Mark Plotkin, an ethno-botanist at Conservation International, worries that knowledge of how to use medicinal plants may be disappearing, 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 . . . [t]he knowledge that's being lost most rapidly is information on healing plants."[51]

Several factors contribute to this dramatic rate of TK loss, including socio-economic and environmental pressures.[52] For example, the environmental pressures that destroy the biodiversity resources that certain indigenous peoples rely on for survival will inevitably increase the rate of loss of the knowledge associated with such biodiversity. Similarly, political ostracism and denial of access to traditional lands will also add to the alarming rate of TK loss. Consequently, a multi-pronged approach is necessary to address the problem of TK loss.

This article, however, will focus on two problems that add to the rate of TK loss: first, the predominance of oral transmission of TK among indigenous peoples and local communities, and second, the rising protectionist trend in which source communities are increasingly restricting access to TK in response to the absence of legal and practical control mechanisms. Although multiple factors drive TK loss, it seems that the combination of lack of codification and a rising protectionist trend plays a unique role.

1. *Predominance of Oral Transmission*

One of the core features of TK is that it is orally transmitted from one generation to the next through kinship and personal relationships.[53] This is not to say, however, that there is no codified TK: South Asian TMK such as Ayurveda and Unani are good

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[51] Goleman, *supra* note 48.

[52] *See* Reyes-García et al, *supra* note 49, at 255.

[53] John K. Githae, *Potential of TK for Conventional Therapy: Prospects and Limits*, *in* GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND THE LAW: SOLUTIONS FOR ACCESS AND BENEFIT SHARING 77, 78 (Evanson C. Kamau & Winter Gerd eds., 2009).

examples of documented TK.[54] However, systematically codified TMK seems to be the exception rather than the rule. The transmission of TK, and more particularly TMK, is usually made through kinship relationships and cultural initiations.[55]

The oral nature of TK lies in stark contrast to modern knowledge in which a culture of systematic documentation and dissemination is the norm.[56] This culture of documentation is observable in various aspects 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,[57] highlighting the pressure on 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 documentation requirements.[58] Examples include the disclosure requirement[59] under patent laws and the copyright law requirement that expressions be fixed in a tangible medium.[60] The absence of a similar culture of codifying knowledge among indigenous peoples and local communities plays a key part in increasing the rate of TK loss. While the knowledge of modern societies continues to exist through books and other mediums of documentation, a considerable portion of indigenous peoples' and local communities' knowledge disappears with the communities.

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[54] *See* WIPO, *Inventory of Existing Online Databases Containing Traditional Knowledge Documentation Data*, at 6, WIPO/GRTKF/IC/3/6, (May 10, 2002).

[55] *See* Carvalho, *supra* note 33, at 244.

[56] OGUAMANAM, *supra* note 27, at 14.

[57] *See generally* Lindley J. Stiles, *Publish-or-Perish Policies in Perspective*, XVII J. TEACH. EDUC. 464 (1966).

[58] Documentation plays a key role in patent and trademark rights, and documentation of literary and artistic works provides the copyright owner with stronger claims. *See* 17 U.S.C. § 401 et. seq. (2012).

[59] 35 U.S.C. § 112 (2012).

[60] 17 U.S.C. § 102 (2012).

2. *A Rising Protectionist Trend*

Exacerbating the problem of TK loss is a rising protectionist trend in which source communities and megadiverse countries[61] take measures to restrict access to TK and genetic resources. This trend seems to have been a response to the lack of effective legal protection for TK and genetic resources. A few scholars have noted,[62] albeit 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 Global South and many knowledge-holder communities see the lack of legal protection as unfair. The protectionist trend adds to the alarming rate of TK loss resulting from the predominantly uncodified nature of TK.

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 bioprospecting 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

> [s]timulated 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.[63]

Restrictions on genetic resources would mean restricted access to TK because of TK's close linkage to genetic resources, and most national legislative acts also mention restrictions on access to TK

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[61] "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. *Megadiverse Countries*, UNITED NATIONS, http://www.biodiversitya-z.org/content/megadiverse-countries (last visited Nov. 5, 2017).

[62] *See* Carvalho *supra* note 33; Cottier & Panizzon, *supra* note *4,* at 757–76 (outlining national legislations enacted to protect TK in India, Brazil, Peru, the Philippines, and the Africa model legislation.).

[63] McManis, *supra* note 5, at 5.

concurrently. The status quo in bioprospecting relationships will not be sustainable if this trend continues and more megadiverse countries legislate to restrict access.

In addition to national restrictions, 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 has the knowledge and skill to identify and investigate therapeutic plants. Although some of these attempts to keep TK secret fail, other measures may be created that will become effective in restricting access. 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.[64]

The fact that megadiverse countries take a protectionist stance on genetic resources and TK may not necessarily be troublesome. If such measures were effective in allowing either the source countries or communities to use the knowledge in producing products and services for the 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. In those instances, both the TK holders and the public lose. In the absence of use, codification, or disclosure, this knowledge base will be lost to the communities and cultures that preserved it for ages.

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[64] Doris Estelle Long, *Trade Secrets and Traditional Knowledge: Strengthening International Protection of Indigenous Innovation*, *in* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 495 (Rochelle C. Dreyfuss & Katherine J. Strandberg eds. 2011).

In summary, the lack of systematic documentation among many knowledge-holder communities contributes significantly to the tragedy that TK faces, especially when combined with the protectionist trend, and other factors such as the continued destruction of knowledge-holder communities and their biodiversity resources. This lack of investment in the codification of TK, despite its considerable value, may seem paradoxical. This is made even more complex by the rising protectionist trend. From the perspective of global public welfare, more access to TK and genetic resources is better rather than increased restrictions. The section below frames these issues within public goods literature to better understand the problem of TK loss and rising protectionism, and to find potential solutions.

E. *Traditional Knowledge as a "Public Good"*

Public goods in economic literature are non-rivalrous (i.e., goods that could be consumed by one person without reducing the ability of another to consume the same good) and non-excludable (i.e., goods from which the producer cannot extract benefits).[65] Knowledge is commonly considered to be a public good and is at times labeled "the quintessential public good."[66] For decades, economists have noted the public-good nature of knowledge.[67] Sharing one's knowledge with another does not lessen the amount of knowledge consumed by each person, and once knowledge is disclosed to the public, it is usually difficult, costly, or impossible

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[65] *See generally* HAL R. VARIAN, MICROECONOMIC ANALYSIS (3rd ed. 1992).

[66] Peter Drahos, *The Regulation of Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 46, 47 (Jerome Reichman & Keith E. Maskus eds., 2005).

[67] *See, e.g.*, 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* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY, & TRADITIONAL KNOWLEDGE (Charles McManis ed., 2007); RAYMOND G. BATINA & TOSHIHIRO IHORI, PUBLIC GOODS: THEORIES AND EVIDENCE 2 (2005), http://link.library.utoronto.ca/eir/EIRdetail.cfm?Resources__ID=444946&T=F (last visited Nov 27, 2014); Joseph Stiglitz, *Knowledge as a Global Public Good*, *in* GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY (Inge Kaul, Isabelle Grunberg, & Mark A. Stern eds., 1999).

to exclude those who do not pay from accessing the knowledge. The public-good nature of knowledge is, for instance, one of the core rationales behind the granting of intellectual property rights over certain inventions and expressions.[68]

As defined in the introductory section, TK refers to the know-how, skills, and practices of indigenous and local communities.[69] Like other information goods, TK could be enjoyed simultaneously by different parties, and once disclosed to outsiders, it would be impossible to exclude them because it is a public good with non-rivalrous and non-excludable features. Because of its public-good nature, TK faces risks similar to those facing other information goods: most relevant, a risk of market failure caused by the reduced capacity of the "producer" to appropriate the benefits of the good (the *inappropriability problem*). While one could help prevent the loss of TK by investing in its codification and disclosure, once the knowledge is disclosed the investor would not have the ability to distinguish those who pay to use the knowledge from those who access it without authorization.

While government intervention is sometimes required to address inappropriability problems with public goods and produce such goods at optimal levels, there are times in which public goods are produced (sometimes at optimal levels) despite being non-excludable.[70] The following section discusses the potential and limitation of some common channels for the production of modern knowledge[71] to incentivize investments in the codification and disclosure of TK. "Investment in the production of a good" in public

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[68] While there are several alternative ways of encouraging investments in the production of public goods, intellectual property rights are one of the key channels through which knowledge production is encouraged. *See* Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 UNIV. CHI. L. REV. 129, 129 (2004).

[69] *See supra* Section I.B.

[70] *See* Varian, *supra* note 65, at 414–15.

[71] Although there is no clear and distinct way to define "modern" knowledge, the paper is using these terms to refer to know-how that does not fit in the definition of TK outlined under section I.B above. In this sense, "modern" knowledge would refer to know-how that is in the mainstream system of modern knowledge governance defined by systemic inquiry and extensive documentation. The terms "modern" and "Western" are used interchangeably in the literature.

goods literature is referred to in this article as investing in the "codification and disclosure of TK."

II. ALTERNATIVE CHANNELS FOR ENCOURAGING INVESTMENT IN TK

Knowledge goods in the modern world have been produced through different channels. These channels include government investment/subsidy, recognition of private rights, secrecy, and group cooperation.[72] While there are other channels that support the production of knowledge goods, these four channels are the most relevant for the production of knowledge goods in general and TK in particular.

A. *Government Provision*

Government provision is a major channel for the production of knowledge goods. A considerable portion of knowledge production in universities, government agencies, and research institutes is publicly funded and contributes significantly to socio-economic development.[73] Government investment in infrastructure for the production of knowledge goods is essential to sustain modern knowledge.[74] Similarly, government supply or subsidy may be necessary for the codification and disclosure of TK; the TK codification attempts initiated by governments in some countries are good examples of this need. The governments of India,[75] China,[76]

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[72] *See generally* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate,* 92 TEXAS L. REV. 303 (2013).

[73] 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 with winning the prize, may be willing to invest their resources in addressing such problems. Some government funds have eligibility requirements that are used to direct research into areas of special public interest. *See* Marlynn Wei, *Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. TECH. L. 25, 25–26 (2007).

[74] *See* Stiglitz, *supra* note 67, at 311.

[75] *See* TKDL, *supra* note 42.

[76] *See* Yanling Sun, *Introduction to China TCM Patent Database*, STATE INTELLECTUAL PROPERTY OFFICE (June 17, 2002), http://www.wipo.int/export/sites/www/tk/en/resources/pdf/china.pdf.

South Korea,[77] South Africa,[78] and Venezuela[79] have invested considerable financial and human resources to collect, organize, document, and manage TK within their jurisdictions.

Despite the potential of government investment/subsidy in supporting the codification of TK, there are issues that could limit this potential.[80] 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.[81] This scenario would involve a free-rider problem which could in-turn reduce the incentives of governments to invest in TK codification and disclosure. Discussing "modern" knowledge production in general, the Nobel Prize-winning economist Joseph Stiglitz rightly argues that the global free-rider problem (in which some countries will try to benefit by taking from

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[77] *See* Jeongyoon Choi, *Introduction of Korean Traditional Knowledge Portal (KTKP)*, KOREAN INTELLECTUAL PROPERTY OFFICE (Mar. 2011), http://www.wipo.int/edocs/mdocs/tk/en/wipo_tkdl_del_11/wipo_tkdl_del_11_ref_t9_4.pdf.

[78] Biffy van Rooyen, *Safeguarding the Future of Indigenous Knowledge Through ICT*, 5 SCIENCESCOPE 24, 25 (2011); Catherine Saez, *South Africa to Launch National Traditional Knowledge Recording System*, INTELL. PROP. WATCH (Oct. 5, 2013), http://www.ip-watch.org/2013/05/10/south-africa-to-launch-national-traditional-knowledge-recording-system/?utm_source=weekly&utm_medium=email&utm_campaign=alerts.

[79] WIPO, *supra* note 54; Stanford Zent & Eglee L. Zent, *On Biocultural Diversity from a Venezuelan Perspective: Tracing the Interrelationships Among Biodiversity, Culture Change and Legal Reform*, *in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY, & TRADITIONAL KNOWLEDGE 91, 105 (Charles R. McManis ed., 2007).

[80] Government investment in the provision of TK may include investments in infrastructure or in investing in the codification of TK itself. *See* TKDL, *supra* note 42; Sun, *supra* note 76*;* Choi, *supra* note 77.

[81] In fact, developing countries pushed for the signing of the Nagoya Protocol because they were unable to enforce access and benefit sharing requirements set out in their law against users in developed countries. *See* Linda Wallbott, Franziska Wolff, & Justyna Pozarowska, *The Negotiations of the Nagoya Protocol: Issues, Coalitions and Process*, *in* GLOBAL GOVERNANCE OF GENETIC RESOURCES: ACCESS AND BENEFIT SHARING AFTER THE NAGOYA PROTOCOL 33, 41–52 (Sebastian Oberthür & G. Kristin Rosendal eds., 2014).

the global pool of knowledge, without contributing their share to it) is cause for concern.[82] He states that this free-rider problem might limit the initiative of some governments to fund global public goods, and posits that the establishment of a global entity that would manage investments in the production of knowledge might help optimize investments in global knowledge generation.[83]

This global 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.[84] 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 sharing the cost. In fact, the risk of free riders seems to be behind the restrictive measures taken by the TK codification initiatives in the TK source countries, noted earlier, whose 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).[85] Access to such databases is provided in a highly restricted manner to patent examiners for the sole purpose of patent examinations.[86] Even if there are "open" databases, they are limited to local uses within the community or the country.[87] Because of the

[82] Stiglitz, *supra* note 67, at 320–21.

[83] *Id*.

[84] Wallbott, Wolff, & Pozarowska, *supra* note 81, at 41.

[85] TKDL, *supra* note 42 (India); STATE INTELLECTUAL PROPERTY OFFICE OF THE P.R.C. http://www.sipo.gov.cn (last visited Oct. 27, 2017) (China); China Traditional Chinese Medicine Patent Database Search System, STATE INTELLECTUAL PROPERTY OFFICE OF THE PRC, http://www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_bkk_09/wipo_iptk_bkk_09_topic5_2.pdf (last visited Oct. 27, 2017); Choi, *supra* note 77 (South Korea); *Korean Traditional Knowledge Portal*, KOREAN INTELLECTUAL PROPERTY OFFICE, http://www.koreantk.com/ktkp2014/ (last visited Oct. 27, 2017).

[86] Traditional Knowledge Digital Library (TKDL) Access Agreement, U.S.-India (Nov. 23, 2009) (Copy with author); Traditional Knowledge Digital Library (TKDL) Access Agreement, Eur.-India, (Copy with author); Ministry of Sci. & Tech., *India and Japan Sign TKDL Access Agreement*, PRESS INFO. BUREAU (Apr. 20, 2011, 6:53 PM), http://pib.nic.in/newsite/erelcontent.aspx?relid=71713.

[87] *See* Saez, *supra* note 78.

lack of active use of these databases, their potential to enhance global social welfare (for instance in bioprospecting[88] projects) is currently not being realized.

A collaborative initiative will be able to solve this inefficient state of affairs. It has been noted that citizens of countries in the Global North benefit considerably from the continued availability of TK and biodiversity resources predominantly sourced from the Global South.[89] This fact should justify a requirement that the North invest in TK codification initiatives taking place in the South in some form. Since benefits that citizens of countries in the Global North receive from TK and biodiversity resources in the South are diffused benefits, it is reasonable that the governments of the Global North should support TK codification in the South in the same way funds collected through taxes are used for diffused public benefits. 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 modern knowledge requires a global framework for optimal production and use,[90] 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

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[88] "Bioprospecting can be defined as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature." WORLD HEALTH ORGANIZATION, TRIPS, CBD AND TRADITIONAL MEDICINES: CONCEPTS AND QUESTIONS. REPORT OF AN ASEAN WORKSHOP ON THE TRIPS AGREEMENT AND TRADITIONAL MEDICINE (2001), http://apps.who.int/medicinedocs/en/d/Jh2996e/6.3.html. Bioprospectors use genetic resources and traditional knowledge of indigenous peoples and local communities to in their research. *Id.* This can be contrasted with the alternative method of producing synthetic compounds or screening samples of genetic resources for active ingredients without the use of traditional knowledge. *Id.*

[89] *See generally* Remigius N. Nwabueze, *Ethnopharmacology, Patents and the Politics of Plants' Genetic Resources*, 11 CARDOZO J. INT. COMP. L. 585 (2003).

[90] Stiglitz, *supra* note 67, at 320–21.

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 needs a complementary source. Although government investment in the infrastructure and substantive codification of TK is promising, it faces considerable limitations that should be addressed through other channels, such as the encouragement of private investments.

B. *Recognition of Private Rights*

The recognition of private rights has encouraged investments in production and dissemination of modern knowledge.[91] Intellectual property rights have arguably encouraged private investments in the production and dissemination of know-how, at least in some industries.[92] Following such measure, advocates of TK protection suggest that recognizing private rights in TK would encourage knowledge-holder communities and/or outsiders to invest in the codification and disclosure of TK.[93] Recognition of a private right would address the *inappropriability* problem by artificially making TK excludable. The public goods nature of TK would be limited, thereby encouraging private investment in the codification and disclosure of TK. This can be expected to encourage the investment

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[91] Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 BERKELEY TECH. L.J. 1009, 1009–12 (2008).

[92] While the impact of intellectual property rights in encouraging innovation is highly debated, industries that involve considerable R & D investment and produce outputs that can easily be copied seem to benefit the most. For example, the pharmaceutical industry responds to the granting of patent rights. *See generally* Kendall W. Artz et al., *A Longitudinal Study of the Impact of R&D, Patents, and Product Innovation on Firm Performance*, 27 J. PRODUCT INNOVATION MGMT 725, 728–37 (2010) (discussing the effects of R&D spending and patents in announcement of new products in multiple industries including in the pharmaceutical industry).

[93] OGUAMANAM, *supra* note 27, at 6–7; CARLOS MARIA CORREA, PROTECTION AND PROMOTION OF TRADITIONAL MEDICINE: IMPLICATIONS FOR PUBLIC HEALTH IN DEVELOPING COUNTRIES (2002), http://apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf.

of considerable financial resources and expertise that users of TK, such as biopharmaceutical firms, hold in TK codification and disclosure. Carefully crafted private rights could be granted to knowledge-holder communities to enable them to enter into collaboration with TK users.

There are two ways in which proponents of property rights approach the issues. The first proposes to protect TK under a "property rule,"[94] while the second is to protect TK under a liability rule.[95] Under such framework, users would be allowed to use TK without asking for consent from TK holders. If and when the use of TK results in a successful product, users are required to compensate TK holders. Such compensation usually takes a form of profit sharing. Given the diversity of interests among stakeholders on the use and dissemination of TK, the adoption of different alternative property rights regimes is suitable. While in some situations requesting consent from rights holders may be feasible, in other scenarios, the multiplicity of rights holders could render a property rule regime ineffective.

However, the recognition of private rights is not without its limitations. Since the recognition of private rights encourages self-interested private actors, users may only be interested in investing in TK that has a readily available commercial value. This may result in the neglect of TK that does not have a readily available commercial value but which may prove to be valuable in the future. To address this shortcoming, TK codification and disclosure should be supported by public sources of funding, including government subsidy and altruistic grants.

C. *Secrecy*

Secrecy is a common channel for the production and use of valuable knowledge by private firms. Scholars have recently pointed

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[94] A right protected under a property rule would give the right holder the power to exclude others from using the right. Injunction could be granted against those that violate such right. Whereas, a right protected under a liability rule only gives the right holder the right to be compensated.

[95] Reichman & Lewis, *supra* note 31, at 337–38; Jerome Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743, 1777–78 (2000).

to the potential of trade secret law as a protection mechanism for TK.[96] The core assumption in such a scenario is that the knowledge producer has the capacity to keep knowledge from being accessed by competitors or the general public. At least in the case of TMK, attempts by TK holders to keep the knowledge secret seem to be the trend rather than the exception. The use 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.[97] Such attempts, at least among some indigenous communities, are mechanisms of TMK appropriation intended to prevent its disclosure to outsiders.[98] However, some of these measures, such as bundling TMK with religious ceremonies, might not be sufficient to restrict access to TMK by outside users as experts in the use of plants for bioprospecting may distinguish between a ceremonious procedure and one intended to extract healing elements.[99] As a measure to effectively exclude outsiders, some indigenous groups refuse to communicate their knowledge and ceremonies with outsiders.[100]

To effectively keep TK a trade secret, knowledge-holder communities would need to expend significant resources to create physical or institutional structure that excludes outsiders or legal expertise to enforce confidentiality when violations occur. Most TK-holder communities will lack such resources. Therefore, keeping outsiders from accessing TMK does not seem to be a feasible route to encourage investments in TMK codification and disclosure.

More importantly, however, stopping outsiders from accessing TK is not a global welfare enhancing solution, i.e., it would still mean that the general public would not benefit from, for instance,

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[96] *See, e.g.*, Long, *supra* note 64; Deepa Varadarajan, *Trade Secret Approach to Protecting Traditional Knowledge,* 36 YALE J. INT'L. L. 371, 375 (2011).

[97] UMAR FARUK ADAMU, MODERN AND TRADITIONAL MEDICINE: CONFLICTS AND RECONCILIATION 54 (2013).

[98] Carvalho, *supra* note 33, at 245.

[99] PETRA EBERMANN, 10 PATENTS AS PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE? A LAW AND ECONOMICS ANALYSIS 129 (2012).

[100] Carvalho, *supra* note 33, at 245.

cheaper drugs. Even if knowledge holders are successful in keeping TK secret, it does not guarantee that the alarming rate of TK loss would be stopped. In fact, secrecy, combined with pressures that continue to destroy the social, economic, and environmental structures of knowledge-holder communities, could increase its rate of loss. For instance, 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, their knowledge dies with them.[101] The fact that access to TMK in many communities is a privilege reserved only 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 use. Some common examples of these pressures include policies of cultural assimilation or "modernization," restrictions on access to ancestral lands, and destruction of ecosystems on which source communities rely.

Furthermore, most knowledge holders do not have the capacity to develop pharmaceutical products to meet national or global demand. As a solution, 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 a secret is risky, due to the chance of confusion on the scope of the license, and the lack of legal guidance that parties may find. Negotiating over uncodified knowledge will also make it harder for parties to draft contracts. These risks might explain the lack of successful collaborations. 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. In contrast, knowledge-holder communities will have a very limited capacity to use their knowledge while ensuring its secrecy.

D. *Group Cooperation*

In intellectual property literature, there are examples of norm-based systems through which knowledge goods are produced by

[101] *See* Reyes-García et al., *supra* note 49, at 255.

high-end chefs[102] and stand-up comedians[103] in the absence of legal intervention. The social sanctions of being ostracized are at times sufficient to deter chefs and comedians from stealing recipes and punch lines. Norm-based systems, such as the production of knowledge goods through group cooperation, provide alternative channels for the production of the public goods of knowledge. When norm-based systems are used, members of a community would be expected to invest in research and development, i.e., the production of knowledge goods, despite the absence of (or despite reduced) incentives in terms of direct personal gain. Norm-based systems, however, seem to require close relationships among community members and repeated interactions in order for social sanctions against deviations to be effective.

These scenarios work because of the close social ties members of such communities have with each other and with their audience, which make the social sanctions effective. 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. Therefore, TK-holder communities would not be able to use social sanctions against users who violate those sanctions in another part of the world. For example, the San people of the Kalahari Desert would not be able to use social sanctions against 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 people would be unable to set up a

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[102] Emmanuelle Fauchart & Eric Von Hippel, *Norm-based Intellectual Property Systems: The Case of French Chefs*, 19 ORG. SCI. 187 (2007), http://web.mit.edu/people/evhippel/papers/French%20Chefs%20WP%201-12-07.pdf.

[103] *See* Dotan Oliar & Christopher Sprigman, *There's No Free Laugh (Anymore): The Emergence of Intellectual Property Norms and the Transformation of Stand-Up Comedy*, 94 VA. L. REV. 1787 (2008).

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.

A "knowledge commons" type of institutional set-up may have some potential. This system would involve self-governing entities formally or informally organized under a clear statement of rights and responsibilities of the members of the commons. A good example of a "knowledge commons" is a patent pool in which patent holders in a certain industry cross-license their patent rights to make it easier to produce products requiring multiple patent inventions. The members of the patent pool agree on the terms of the commons such as membership and scope of rights. Many successful knowledge commons involve parties that have legally recognized and enforceable rights.[104] Although informal self-governing knowledge commons have the potential to facilitate bioprospecting partnerships, the absence of a defined legal backdrop and the considerable power imbalance between stakeholders (biopharmaceutical firms and source communities) may affect the success of a TK commons. However, the potential for a knowledge commons approach requires a detailed study to assess its potential and limitations.

E. *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.[105] Therefore, the deterrence from copying that exists in advanced industries does not apply to 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 to. In the case of TK, because of

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[104] GOVERNING KNOWLEDGE COMMONS (BRETT M. FRISCHMANN, MICHAEL M. MADISON, & KATHERINE J. STRANDBURG eds., 2014).

[105] EBERMANN, *supra* note 99, at 129.

its incremental nature, it seems unlikely that such channels would bring about a sufficient commercial advantage necessary to encourage investment in TK codification and disclosure.

From the analysis of alternative channels provided above, the recognition of private rights seems to hold a strong potential to encourage private actors to collaborate with TK-holder communities in the codification and disclosure of TK. This does not mean that it is the only channel that should be adopted. In fact, the recognition of private rights will need to be supplemented by public investment and secrecy in order to address the urgent and complex problem of TK loss. While the adoption of a diverse approach is encouraged, it seems necessary to provide a detailed examination of what a "private rights" alternative could look like as a TK governance framework. Thus, the following sections are devoted to outlining how such a channel could be applied in the case of TMK.

III. A COMMUNAL RIGHTS BASED FRAMEWORK: ONE OF MULTIPLE ALTERNATIVES

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.[106] The bioprospecting right described in the following section 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 and 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,[107] could also be implemented to address the concerns of communities who prefer to opt out of the proposed regime.

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[106] Graham Dutfield. Professor of Int'l Governance, Univ. of Leeds, Emerging International Law Issues Related to Biodiversity, Traditional Knowledge & Cultural Expression: From Community Knowledge to a Knowledge Community (May 2015).

[107] *See generally, e.g.*, Long, *supra* note 64; Varadarajan, *supra* note 96.

A. *Definition and Purpose of the Bioprospecting Right*

The bioprospecting right proposed in this article is a cluster of rights that emanate from bioprospecting activity based on TMK. Depending on the type of TMK database, it includes an exclusive right to conduct bioprospecting, 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 could access. The two types of databases and rights emanating from them are discussed in detail in section III.D.1 of this article.

The purpose of granting the bioprospecting right is to encourage the codification and disclosure of TMK. This "incentive to codify" rationale has two sides: the supply side and the 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.

B. *Core requirements*

While it may be relatively easier to make a case for the granting of rights to source communities, the scope and conditions of these rights are the more contentious aspects. In order to craft a workable framework, parameters must be set which outline the steps needed to 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-holder community, a representative of the community, or a person who has received Prior Informed Consent (PIC) from the knowledge-holder community. Here, one can imagine that source communities will have legal representation through which the community's

relationship with outsiders is handled. 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 proper consent from the knowledge-holder community. Such a requirement is necessary to reverse the protectionist trend, in which TK holders are becoming increasingly restrictive in providing access to their TK and genetic resources. Allowing anyone to receive rights over TMK without receiving consent from knowledge-holder communities will further encourage a protectionist trend and affect the sustainability of the bioprospecting industry. These are the very scenarios the proposed regime seeks to avoid.

To facilitate relationships between knowledge-holder communities and outsiders interested in applying for TMK codification, it is advisable to establish guidelines for how consent is received from a knowledge-holder community. 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,[108] which was signed to explain the Convention on Biodiversity, calls on member countries to establish standards for the "prior informed consent or approval and involvement of indigenous and local communities" (PIC) in access to genetic resources and associated TK.[109] Since the goal in the bioprospecting right proposed in this article is to empower TK-holder communities and to create 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-holder community, must have entered into a benefit-sharing agreement with the knowledge-holder community. As with PIC, a

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[108] *The Nagoya Protocol on Access and Benefit Sharing*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/abs/text/default.shtml (last visited Oct. 26, 2017).

[109] *Id.* at art. 5–7.

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."[110] This framework could be used as a base to build an equitable benefit sharing guideline. Source communities could, however, negotiate for more terms and conditions than those listed in the minimum standards. Reference to other licensing regimes would be helpful here as a reference point. Legal representation will also be helpful here. 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 entered into agreements without understanding the nuances and implications of the agreement.[111]

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 define compared to physical properties, 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 by patent laws should not, however, be required in the case of TMK. 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.[112] A system of protection which adopts a

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[110] *Id*.

[111] For example, the use of Rosy Periwinkle for Leukemia has resulted in multiple source communities and their allies requesting benefit sharing. *See generally* OSSEO-ASARE, *supra* note 1, at 31.

[112] Carvalho, *supra* note 33, at 261.

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 knowledge-holder community does and how to replicate it.[113] 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 may discourage significant follow-on innovation. 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).

In regard to 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 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 communities that can prove to have created and developed the TMK. TMK databases would also be able to facilitate the establishment of joint rights.

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[113] *Id.*

C. *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 of the Goodya plant 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.

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The Fan people—a community in a remote corner of the world—use the Goodya plant to treat depression. Before this traditional treatment begins, the patient must first undergo a three-week training in which she learns 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 spirits of ancestors are 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 Conga, 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. 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 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 fulfill the first core requirement of the bioprospecting—that of Prior Informed Consent[114] of the Fan people as set out in the Nagoya Protocol.

Determining what types of uses infringe upon the bioprospecting right and which uses are legal will be challenging. Here, it may be helpful to adopt the "substantial reliance" test suggested by William Fisher.[115] According to the test, source communities would have rights against users who relied *substantially* on TMK in the production of inventions, products, and processes.[116] It is acknowledged that the substantial reliance standard is a vague one that does not give sufficient direction regarding what types of uses will amount to infringement.[117] However, the vagueness is necessary to allow the proposed mechanism to cover the diverse ways in which

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[114] BIOLOGICAL DIVERSITY, *supra* note 108, at art. 6.

[115] William Fisher, *Two Thoughts About Traditional Knowledge*, 70 L. & CONTEMP. PROBS. 131, 133 (2007), http://dlc.dlib.indiana.edu/dlc/bitstream/handle/10535/3232/Two_Thoughts_About_Traditional_Knowledge.pdf?sequence=1&isAllowed=y.

[116] *See supra* Section III.B.

[117] Fisher, *supra* note 115, at 133.

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."[118] Acts that are substantially similar to those stated in the patent claim would be considered infringements. The substantial reliance standard in TK use 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 III.D.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 must clearly state what the knowledge is in as much detail as possible.[119] In the case of the Goodya plant, the documentation should provide the traditional and scientific name of the plant, how the 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 III.D.1 below.

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[118] *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 38 (1997) (quoting Machine Co. v. Murphy 97 U.S. 120, 125 (1877)).

[119] *See supra* Section III.B.

The final core requirement is that the knowledge should not already be widely diffused.[120] 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 any of this is already widely diffused. A challenging task here is 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 still both secluded from mainstream communities, there is still value in protecting this knowledge in order to encourage its codification and disclosure. The two communities could be considered co-owners. However, the more mainstream the communities are, i.e., the closer they are to 'modern' lifestyles, the more communities there are that potentially hold the knowledge, and the narrower the scope the bioprospecting right should be. 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 the 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

[120] *See supra* Section III.B.

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.

D. *Scope of the Bioprospecting Rights*

Following the discussions regarding the conditions of the bioprospecting right, the scope of such right is the other key issue that needs to be resolved. Economics literature suggests that exclusive rights on knowledge goods increases the cost of follow-on innovation and can deter it altogether.[121] Therefore, the granting of exclusive rights over such goods should be justified through the 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.[122] It is not an easy task to investigate the correct 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.

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.[123] Any attempt to establish an optimal scope for TMK is only made harder because the market has not yet fully responded to TMK.[124] The exact scope of the right will be greatly affected by the policy

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[121] *See* Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND J. ECON. 20 (1995).

[122] Richard A. Posner, *Intellectual Property: The Law and Economics Approach*, 19 J. ECON. PERSP. 57, 59–60 (2005).

[123] *Id*. at 58–59.

[124] Carvalho, *supra* note 33, at 268.

objective of the country adopting the regime.[125] 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 factors to prioritize based on the jurisdiction's interests.

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 if so, 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 unjustifiably broad.

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 define. Despite this challenge, the law has been able to set out legal "fences" that set out the breadth of rights over intangible property.[126] 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, use, and sell the patented invention.[127] The breadth of a patent right depends on the specific claims that are approved by the patent office.[128] Users

[125] It should be noted here that countries that have a record of mistreating their indigenous population may not be receptive to a strong scope of protection. The international minimum standards outlined in the preceding sections could counter such tendencies. Additionally, the benefits that the country would receive from users outside such country could convince governments against setting up an unfair system.

[126] For patentable subject matter, see 35 U.S.C. § 101 (2012).

[127] *Id*. § 271.

[128] *Id*. § 112.

who make, use, or sell inventions covered under a claim would thus be infringing upon the patent right.[129] 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 reach 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. Below, two types of TMK databases and the rights that may arise from them are analyzed.

a. *Two Types of Databases*

The scope of a bioprospecting right would depend on the type of disclosure (i.e., the type of TMK database). There would be two types of databases: (1) a publicly accessible database and (2) 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 with regard to the accessibility of their knowledge.

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

However, some knowledge-holder communities and their licensees may be opposed to the public disclosure of their TMK. Communities may seek to keep their TMK secret because disclosure or commercialization is against their worldview. 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

[129] *Id.* § 271.

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 databases 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,[130] which do 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 knowledge from falling into the hands of unauthorized persons.[131] The absence of sophisticated requirements for protection makes trade secret regimes the apparent candidate for TMK protection. However, the core problem identified in this article—the alarming rate of TMK loss—would not be sufficiently addressed through such regimes because 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 the legal framework. 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

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[130] *See* Long, *supra* note 64; Varadarajan, *supra* note 96.

[131] *See* UNIF. TRADE SECRETS ACT § 1.4 (NAT'L CONF. OF COMM'RS ON UNIF. STATE LAWS 1985), http://www.uniformlaws.org/shared/docs/trade%20secrets/utsa_final_85.pdf.

negotiation. It will also encourage communities not interested in commercializing TMK at all to invest in documenting their TMK to prevent its loss. These types of databases could be used as a repository of TMK and as evidence of its existence and ownership.

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-holder community or their representative. The information could include the name and contact address, any rules and practices that must 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.

b. *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.

There are two alternative frameworks for granting the right over TMK disclosed in a publicly available database. The first grants source communities an exclusive right to undertake bioprospecting based on the publicly disclosed TMK. The right would include the exclusive right to make, use, and 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 either 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 could also be used.

If such a 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. The uncertainty related to measurements of licensee fees could increase the transaction costs involved. The system would benefit both knowledge-holding communities and firms if this risk could be mitigated.

In patent laws of several jurisdictions, there are doctrines designed to reduce the incentive to over claim.[132] 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."[133] To benefit from the doctrine of sound prediction, patent applicants have to show, through a combination of factual statements and sound line of reasoning, that the claimed invention could be expected to do what the patent claims.[134] 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.[135] 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 article. 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. Therefore, the feasible alternative for users is to create

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[132] 35 U.S.C. § 111 (2012).
[133] *Id.* § 112.
[134] *Id.*
[135] *Id.*

a royalty-based agreement in which benefits are shared only where the substantial reliance in the disclosed TMK results in a successful drug.

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, rights holders would have the claim 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. Jerome 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.[136]

There is a risk of over-claiming within this 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 on the publicly disclosed TMK. Because there is limited chance that TMK, which 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 over-claim, they have to overcome the challenging burden of proving that users relied substantially on 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

[136] Reichman, *supra* note 95; Reichman & Lewis, *supra* note 31. Section VI of this paper on "Building Stakeholder Buy-in" outlines steps that should be taken to safeguard against abuse of the system by users and enabling source communities to build trust in the system. *See infra* Section VI.

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 to ensure fair compensation. Anyone can access the publicly available database, use it to produce a product, and claim to have not relied on the TMK. To mitigate this 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 an 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 can also be expected to reduce the transaction costs involved in 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 Reichman has argued.[137] 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 of a successful bioprospecting process is preferred. This will greatly reduce the incentive to over claim and can be expected to facilitate investment and innovation in bioprospecting projects. The reduction of

[137] Reichman, *supra* note 95; Reichman & Lewis, *supra* note 31.

transaction costs should also facilitate bioprospecting partnerships between users and source communities.

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.[138] 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, as decided by the appropriate community representative, 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.*,[139] 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.[140] The court declared that because of the way the common law has developed in the area, the suitable remedy for a particular case could emanate from equity, contracts, torts, or property.[141] 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, since most knowledge-holder communities

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[138] 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.

[139] Cadbury Schweppes Inc. v. FBI Foods Ltd., [1999] 1 S.C.R. 142 (Can.), http://www.canlii.org/en/ca/scc/doc/1999/1999canlii705/1999canlii705.html.

[140] *Id.*

[141] *Id.*

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 spring-board principle adopted in the *Schweppes* case may be beneficial. If courts adopt this 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).[142]

The above section outlines what the breadth of the bioprospecting right may be in theory. The following section examines a practical case that adopts a similar framework. The World Intellectual Property Organization (WIPO) has developed a robust classification of TK which speaks to the different levels of diffusion entailed in TK and the different potential rights that may be available.[143] 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.

c. *WIPO's Draft Framework*

The WIPO has grouped the potential status in which TK may be found and the possible alternative rights that knowledge holders might be interested in (table reproduced below).[144] Such mechanism could be modified for use in the bioprospecting rights outlined in this article to meet the needs of the jurisdiction that is considering adopting the mechanism.

In the 'nature of TK' row, the tool categorizes TK 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,[145] protection against unfair competition, and

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[142] *Id*.

[143] WEND WENDLAND, WORK IN THE WORLD INTELLECTUAL PROPERTY OFFICE - INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY, AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE (2015), http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf.

[144] *Id.*

[145] 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

compensation or benefit sharing. At times, the nature of the knowledge might determine the best right. 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.

	Nature of TK	Secret	Closely held	Publicly available	Widely diffused
Nature of rights					
Exclusive property rights					
Moral rights					
Unfair competition					
Compensation/ benefit sharing					

Table 1: WIPO's Draft Framework for TK Protection[146]

2. *Term of Bioprospecting Right*

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

the integrity of a work, and the right to publish a work anonymously. Moral rights originated in the civil law legal system and, although limited, are recognized in common law legal systems. Michael Rushton, *The Moral Rights of Artists: Droit Moral ou Droit Pécuniaire?*, 22 J. CULT. ECON. 15 (1998).

[146] WENDLAND, *supra* note 143.

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-holder communities disclose 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 source community. 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 ceased 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 documentation could cease 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 TMK,[147] 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 a 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 diverse

[147] Many developing countries and the African Group have advocated for perpetual rights over TK. *See* UNCTAD-ICTSD PROJECT ON IPRS AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 399 (2005).

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 systems.

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 the 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.[148] However, the incremental effect of an additional year of protection will diminish as the term increases.

The purpose of establishing the bioprospecting right is to encourage the codification and disclosure of TMK. However, as it has been noted throughout this article, 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. Thus, a set of alternative frameworks that give stakeholders some flexibility would be suitable.

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 domestic legal 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.

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[148] WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 76 (1969).

Although most economists recommend term limits for intellectual property rights,[149] there is little evidence to indicate the optimal term for intellectual property rights in general.[150] In most countries, standard patent terms are for 20 years from the date of the application for a patent.[151] 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.[152] This implies that the optimal term for patent protection depends on the subject matter of protection.[153] Therefore, it may be worthwhile to investigate the efficiencies involved in differing terms for different TMK contributions to bioprospecting.[154]

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; however, the administrative costs would make such a system inefficient.[155] Similarly, a case-by-case analysis of optimal protection for TMK may be inefficient.

a. *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 some factors 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 a term.

One core factor to consider is the incentivizing effect that patent law has had on the codification and disclosure of modern

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[149] *Id*.

[150] ROBERT D. COOTER & THOMAS ULEN, LAW AND ECONOMICS 131 (5th ed. 2008), http://www.loc.gov/catdir/toc/ecip0718/2007021468.html (last visited Jun 23, 2015); *see also* Posner, *supra* note 122, at 59.

[151] *See, e.g.*, 35 U.S.C. § 154 (2012).

[152] According to the World Intellectual Property Organization there are fifty-eight countries and African Regional Intellectual Property Organization that provide special protection for utility models or petty patents. *Where Can Utility Models Be Acquired?*, WIPO, http://www.wipo.int/sme/en/ip_business/utility_models/where.htm (last visited October 26, 2017).

[153] COOTER & ULEN, *supra* note 150, at 131.

[154] Reichman & Lewis, *supra* note 31, at 354.

[155] COOTER & ULEN, *supra* note 150, at 132.

inventions.[156] 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.[157] By "sub-patentable innovation" Reichman and Lewis are referring to improvements on existing knowledge that are not advanced enough to receive patent protection.[158] Both the equity and accretion rate rationales seem to have some force, and both have implications for the incentive to codify and disclose.[159] 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 a longer term if the right is to be sufficient to encourage the documentation and disclosure of TMK.[160]

Although Reichman and Lewis do mention the term of twenty years in the hypothetical they use, they avoid suggesting what the term should be.[161] In most countries, present-day sub-patentable innovations[162] such as petty patents or utility models receive protection for seven to ten years.[163] Article 38 of the Trade-Related Aspects of Intellectual Property (TRIPs) allows member countries to provide protection for up to fifteen years for "layout designs (topographies) of integrated circuits."[164] Because of the low standalone value of TMK, it seems that the term of protection should

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[156] For a detailed discussion of how patent laws encourage the codification and disclosure of "modern knowledge," see Burk, *supra* note 91.

[157] Reichman & Lewis, *supra* note 31, at 359.

[158] *Id*.

[159] *Id*.

[160] For a general discussion on the standalone value of an invention and its effect on the optimal term of protection under patent law, see Suzanne Scotchmer, *Standing on the Shoulder of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

[161] Reichman & Lewis, *supra* note 31, at 359.

[162] This term is used to refer to inventions that do not qualify as a patent but are still useful enough.

[163] Reichman & Lewis, *supra* note 31, at 359.

[164] TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) Art. 38 (3), Apr. 15, 1994, Annex IC 1569 U.N.T.S. 299, 33 I.L.M. 1197 (1994), https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

indeed be longer than other sub-patentable innovations that have a readily available commercial value.

Another factor that should be considered in deciding what term limits to adopt is the average time it takes to produce a successful drug using TMK. The proposed term of protection should be longer than the average bioprospecting time 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 likely only 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 research and development 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 length of the drug discovery process has been estimated to be twelve to fifteen years.[165] This is a general estimate that does not take into consideration the use of TMK in this process. Therefore, the use of TMK might reduce this timeline significantly. However, it is not easy to estimate by how much this timeline would be reduced. More research is required to show what the duration of average drug discovery would be when TMK is used. Despite the uncertainty related to the average time the process may take, the currently available twelve- to fifteen-year 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 often recouped is seen as a major problem in the biopharmaceutical industry.[166] Therefore, researchers would have to consider a similar risk in cases of bioprospecting projects when setting term limits.

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[165] JP Hughes et al., *Principles of Early Drug Discovery*, 162 BR. J. PHARMACOLOGY 1239, 1239 (2010).

[166] Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, 9 NAT. REV. DRUG DISCOVERY 203, 203–14 (2010).

A third analogy that could be used in setting terms for the proposed bioprospecting right is the term used for data and marketing exclusivity. Data exclusivity refers to the protection extended to pre-clinical and clinical test data used in the drug approval process from use by other firms applying for regulatory approval.[167] An additional exclusive right, market exclusivity, refers to the exclusive right given to original manufacturers to market a drug before competing generic versions are allowed to be marketed.[168] Both exclusive rights could work independently or alongside patent rights, which means at its maximum the collective exclusive right could be set at twenty years plus the period of data and market exclusivity.

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 of exclusivity to Orphan Drugs (ODE) and five years for New Chemicals (NCE).[169] In the European Union, the term has been harmonized (for applications filed after November 2005) to 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."[170] Therefore, the term of exclusivity in the EU can extend to eleven years from the initial marketing approval by the original applicant.[171] In Canada, the term is between six to eight years depending on specific factors.[172] Up to thirty-one years of exclusivity can be acquired as the maximum term resulting from the combination of twenty years of patent rights with up to eleven

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[167] Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 2 (2009), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2860741/.

[168] *Id*.

[169] FDA Drugs for Human Use, 21 C.F.R. § 314.108 (1999).

[170] Directive 2001/83/EC of The European Parliament and of the Council on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. L. 311.

[171] *Id*.

[172] *See* Food and Drug Regulations, C.R.C., c 870, C.08.004.1(3) (Can.), http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf.

years of exclusivity (at least in the EU).[173] In addition to these general terms of exclusivity, there are also 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 jurisdiction and the subject matter involved. Although these terms are related to bioprospecting because they deal with the drug discovery process, data and market exclusivity become relevant in later stages of the drug development process, whereas bioprospecting happens in the early stages. Thus, the terms of protections being provided for data and market exclusivity may not be 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 groups that successfully lobby governments, which make existing terms less useful as a reference. Despite these considerable shortcomings, these terms 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.[174]

b. *Perpetual Bioprospecting Right?*

Indigenous and local communities are heterogeneous and therefore have different worldviews from each other. Some communities may not recognize the concept of term limits on their knowledge.[175] 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 even considered to be part of the cultural identity of some communities. Therefore, the idea of losing control over the knowledge following the expiration

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[173] Parliament and Council Directive on Medicinal Products for Human Use, *supra* note 170.

[174] RESOURCE BOOK ON TRIPS AND DEVELOPMENT, *supra* note 147, at 399.

[175] Many developing countries and the African Group call for perpetual rights over TK. *See id*.

of a set term may be alien, and unattractive, to some.[176] However, losing control does not mean losing the ability to continue to use and apply their knowledge; it only means that communities will not be able to regulate the use of their knowledge by others. Even in this sense, some communities still may not be enthusiastic in codifying and disclosing their knowledge to outsiders who might use such knowledge in ways that offend the community.

Proposals for perpetual intellectual property rights over know-how are very rare. There does not seem to be any Western jurisdiction with a perpetual patent system. Terms differ from one community to another, but every jurisdiction seems to have term limits. The U.S. Constitution goes to the extent of expressly calling for term limits on such rights.[177] The U.S. 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."[178] It seems clear from such statements that term limits are inherent in the American concept of patents. Other intellectual property rights such as trademarks and the protection of secret information do not have specified term limits.[179] Such a right could be considered perpetual so long as certain conditions continue to be fulfilled.

For example, there have been calls for perpetual copyright.[180] However, such proposals have been strongly criticized for misunderstanding the nature of intellectual property rights.[181] The case for perpetual intellectual property rights is hard to make, particularly in the case of patent rights. The scope of patents is

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[176] Zent, *supra* note 79, at 140.

[177] U.S. CONST. art. I, § 8, cl. 8.

[178] *Id*. (emphasis added).

[179] 15 U.S.C. § 1059 (2012); *see also* UNIF. TRADE SECRETS ACT, § 1(4) (outlining the requirements of trade secret protection).

[180] Mark Helprin, *A Great Idea Lives Forever. Shouldn't Its Copyright?*, N.Y. TIMES (May 20, 2007), http://www.nytimes.com/2007/05/20/opinion/20helprin.html.

[181] *Against Perpetual Copyright*, THE LESSIG WIKI (Sept. 22, 2014, 7:29 PM), http://wiki.lessig.org/Against_perpetual_copyright.

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. Because 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 a perpetual bioprospecting right because 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.

c. *Analogy to Database Protection*

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.[182] The core purpose of the EU database directive is economic efficiency.[183] It is intended to correct the market failure that results from the non-excludable nature of information goods documented in databases.[184] Article 10 of the directive sets fifteen years as the term limit for the protection of databases.[185] The directive goes further to state the following:

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[182] *See* Directive 96/9/EC of the European Parliament and of the Council on the Legal Protection of Databases, 1996 O.J. L. 77/20, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0009:EN:HTML (last visited Jul 2, 2015).

[183] *Id.* at preamble, ¶ 1–4.

[184] *Id.* at ¶ 7.

[185] *Id.* at art. 10(1).

> 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.[186]

Adding substantially new content to a database gives rise to a new term of fifteen years for such databases.[187] Therefore, a dynamic database would provide continued protection for substantially altered content. It is possible to apply such a practice to the proposed *sui generis* TMK system. In these cases, continued protection for dynamic TMK databases would be allowed so long as the information is substantially altered.[188] However, such an analogy 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.

d. *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.[189] It bears some resemblance to the interest of some knowledge holders for perpetual rights. The domaine 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.[190] 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 domaine public payant

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[186] *Id*. at art. 10(3).
[187] *Id*.
[188] Carvalho, *supra* note 33, at 261.
[189] Reichman & Lewis, *supra* note 31, at 362.
[190] SILKE VON LEWINSKI, INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND FOLKLORE 84 (2008).

in their jurisdictions and forty-six members responded.[191] Of the forty-six countries that responded, a minority (twelve countries) confirmed that they had systems that resembled a paying public domain.[192] This obligation to pay for public domain material is a perpetual obligation in almost all of these jurisdictions[193] and takes the form of a small percentage of the selling price of the product.[194] It should be noted, however, that some jurisdictions have a short list of the types of works covered under such system.[195] The royalties collected through such a system are either paid directly to associations of authors of works or to the state which, in turn, forwards at least some of the payment to such associations.[196] The application of a paying public domain to traditional knowledge[197] that has already fallen into the public domain is supported by some scholars and has already been adopted by some developing countries.[198]

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" to compensation exists, it is known only in a handful of jurisdictions,[199] and the right relates only to

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[191] UNESCO & WIPO, ANALYSIS OF THE REPLIES TO THE SURVEY OF EXISTING PROVISIONS FOR THE APPLICATION OF THE SYSTEM OF "DOMAINE PUBLIC PAYANT" IN NATIONAL LEGISLATION (1982), http://unesdoc.unesco.org /images/0004/000480/048044EB.pdf.

[192] *Id.*

[193] "With the exception of Bulgaria, where the domaine 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 *Domaine Public Payant*, UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION (1949), http://unesdoc.unesco.org/images/0014/001439/143960eb.pdf.

[194] *Id*. (illustrating that most of the jurisdictions adopt a royalty rate in the range of 2–10% of the selling price of the product).

[195] *Id*. at 1.

[196] *Id*. at 2.

[197] The term 'traditional knowledge' is broadly defined by some scholars to include traditional cultural expressions.

[198] LEWINSKI, *supra* note 190, at 84; Reichman & Lewis, *supra* note 31, at 358.

[199] UNESCO & WIPO, *supra* note 191.

expressions.[200] Secondly, rights over expression (such as copyrights) are relatively shallow because there are alternative ways of expressing the same idea. Patent rights are broad because acts of infringement do not have to be exact imitations.[201] Indeed, in the US 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."[202] 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.[203] The subject matter of protection discussed in this article 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)[204] exists, proposing such a term for the bioprospecting right is unjustified because of the difference between the two rights discussed above.

There is little literature that shows the efficiencies of adopting a perpetual economic right over know-how.[205] 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.

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[200] 17 U.S.C. § 102 (2012).

[201] While the scope of protection in copyrights is limited to the expression (17 U.S.C. § 102 (2012)), protection under patent law covers the claimed invention. *See* 35 U.S.C. § 112 (2012).

[202] *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 38 (1997) (quoting Machine Co. v. Murphy, 97 U.S. 120, 125 (1877)).

[203] Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 160–61 (1989); *see also* comment accompanying UNIF. TRADE SECRETS ACT, § 1(4)(ii).

[204] *See* 17 U.S.C. § 301 et. seq. (2012).

[205] Posner, *supra* note 122, at 61.

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. The longest any substantive right should last is for the period the knowledge-holder community continues to exist. A perpetual bioprospecting right over TMK is unwarranted in the economic terms discussed in this article. The dynamic efficiency gains would not be more than the static inefficiency gains if the right is a perpetual right because the static inefficiency will continue to increase while the dynamic efficiency gains will decrease over time.

e. *Concluding Remarks on Term of Right*

Economic 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.[206] 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 increase.[207] 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 and dynamic efficiency.[208] Even if there were no dynamic costs (i.e., negative effects on follow-on innovation), the static costs, such as higher prices, might 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., seven to ten years), given the limited standalone value and slow accretion rates for TMK. It

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[206] NORDHAUS, *supra* note 148, at 76.

[207] *See* Posner, *supra* note 122, at 59–60; Suzanne Scotchmer & Jerry Green, *Novelty and Disclosure in Patent Law*, 21 RAND J. ECON. 131, 145 (1990).

[208] Arti Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 853 (2001).

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 aforementioned twelve- to fifteen-year estimated timeline for general drug discovery 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 three to ten years.[209]

In terms of the range within which policymakers could fix term limits, a minimal protection of twelve to fifteen 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."[210] The proposals for perpetual bioprospecting rights over TMK may not be justified when seen through an economic efficiency lens. It may be justifiable to provide 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.

Because of the challenges in determining optimal terms, further theoretical and empirical research into, among other things, the average time it takes 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 terms of protection in encouraging the codification and disclosure of TMK, on the one hand, and for follow-on innovation on the other.

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[209] Reichman, *supra* note 167, at 2.
[210] LEWINSKI, *supra* note 190, at 521.

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.

IV. NATURE AND SCOPE OF CODIFICATION AND DISCLOSURE

Critics often focus on the nature and scope of TMK codification.[211] Some commentators argue that codification would remove the knowledge from its environmental and cultural context, thereby disrupting its original setting.[212] However, such criticism misses the fact that it is possible to provide cultural and environmental context while codifying TMK. This criticism also disregards the fact that knowledge can be codified without limiting the ability of knowledge holding communities to continue using their TMK in accordance with tradition. Because TMK faces an alarming rate of loss, imperfect codification is preferred over oblivion. In this spirit, the following section discusses the scope of TMK codification.

A. *Holistic Codification*

Although the nature and scope of TMK codification could vary according to the capacity and culture of knowledge-holder communities, preferably codification should be holistic. 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 increase the value of the codification in other 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

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[211] *See* DOCUMENTATION OF TRADITIONAL KNOWLEDGE AND TRADITIONAL CULTURAL EXPRESSIONS, WIPO, http://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_9.pdf (last visited Nov 5, 2017).

[212] *See generally* JAMES C. SCOTT, SEEING LIKE A STATE: HOW CERTAIN SCHEMES TO IMPROVE THE HUMAN CONDITION HAVE FAILED 24 (1998).

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 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 cost could be offset by the increased value (both monetary and non-monetary) of holistic codification. However, codification of the available resources and at whatever level of detail is still more valuable than letting the knowledge disappear. Thus, codification should be encouraged 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.

B. *Scope of Codification*

As a general principle, the preferred system of codification is a broad one rather than narrow. While narrow TMK codification would provide basic information, such as the name of the resource

and its use, broad TMK codification would add details such as where the plant resource is located, what time of the year it grows, and what exact steps are used to extract the resources. It would also include supporting documents collected or created by a multi-disciplinary team made up of traditional healers, elders, anthropologists, scientists, technology experts, etc. 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.

Here, it is instructive to revisit the hypothetical case of the Fan people and their Goodya plant to 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 the information that a narrow codification provides.

On the other hand, a broad codification would attempt to codify as much information as possible given available resources. For instance, it could include the historical and cultural meaning Goodya has for the Fan people. It would specify the location in which Goodya grows, including GPS coordinates, 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 could 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 can learn from existing databases and attempt to overcome their existing limitations such as their defensive/restrictive orientation, abiding by an international standard system classification. Perhaps the most famous TMK database is the Indian Traditional Knowledge Digital Library (TKDL).[213] 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.

C. *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.[214] Although the amount of information included in the database is impressive, it is currently only being used defensively to invalidate non-inventive patents.[215] A more proactive use of the knowledge documented in the database would have considerable global welfare-maximizing potential. The accessibility of these three million transcripts to researchers can be expected to result in increased efficiency in research and development of biopharmaceutical products and services.[216]

One sample of the information documented in the TKDL might help explain what a broad TMK codification should look like. The

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[213] TKDL, *supra* note 42.

[214] *Source of Information*, TRADITIONAL KNOWLEDGE DIGITAL LIBR. (INDIA), http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng (last visited Nov. 5, 2017).

[215] The restrictive nature of the TKDL is seen by the many agreements the Indian government entered into with patent offices around the world. *See*, *e.g.*, TKDL Access Agreement, *supra* note 86.

[216] The use of the Hoodia extract P57, mentioned at the beginning of this paper, is a good example of the advanced research that could take place based on the input of TMK at the initial stages. Although a pharmaceutical drug has yet to be developed using the compound P57, one can imagine that the drug development process would benefit considerably if the thousands of documented TMK sources were made easily accessible to scientists. *See supra* Section I.A.

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.[217] 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.[218] 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 zeylancicum Blume (cinnamon), Crocus sativus Linn. (saffron crocus, saffron), Granular sugar

2. Therapeutic composition/formulation is mentioned below:

1 santalum album Linn. (sandalwood)

- 9 gm

2 Silk Cocoon

- -shredded 9 mg

3 Onosma bracteatum

Flower 12 gm

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[217] *Patent 2667831 Summary*, CANADIAN INTELL. PROP. OFF., http://www.ic.gc.ca/opic-cipo/cpd/eng/patent/2667831/summary.html?query=(Composition+Containing+Ginseng+and+Cinnamon)&start=1&num=50&type=advanced_search (last visited Oct. 29, 2017).

[218] *Id*.

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

5. Nymphaea alba Linn. (European white water-lilly, 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 semisolid 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.[219]

While the last communications on file show that the patent is in a "state of abandonment,"[220] the official administrative status shows it is a "dead application."[221]

The TKDL seems to be somewhere in the spectrum halfway 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

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[219] *Patent Document 2642184: Prosecution-Amendment Page, Exhibit 5*, CANADIAN INTELL. PROP. OFF., http://www.ic.gc.ca/opic-cipo/cpd/ (last visited Oct. 29, 2017).

[220] *Patent 2667831 Summary*, *supra* note 217.

[221] *Patent 2642184 Summary: Admin status*, CANADIAN INTELL. PROP. OFF., http://www.ic.gc.ca/opic-cipo/cpd/eng/patent/2642184/summary.html?query=2642184+&start=1&num=50&type=basic_search (last visited Oct. 29, 2017).

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.

One of the major achievements of the TKDL is its creation of the Traditional Knowledge Resource Classification (TKRC). The TKRC, which imitated the International Patent Classification (IPC),[222] was developed in response to the lack of organization in documenting Indian TK. As can be seen in the example above, the database references both the TKRC and the IPC in each transcription. This database will be highly useful for users and knowledge-holder communities to easily locate the resources. 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. In addition to disclosing TMK, the TKRC will make it much easier for researchers to locate the TMK and the specific health issues it has been used to address.

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 more accessible, such as digitizing the database and translating the contents to several global languages.[223] The content of the database has been translated into six languages: English, French, Spanish, German, Japanese and Hindi.[224] 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.

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[222] *Traditional Knowledge Resource Classification (TKRC)*, TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL), http://www.tkdl.res.in/tkdl/langdefault/common/TKRC.asp?GL=Eng (last visited June 24, 2015).

[223] TKDL, *supra* note 42.

[224] *Id.*

Moreover, 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.[225] This is valuable as it allows users to successfully replicate the traditional ways of producing the mixture, which is one of the first challenges in bioprospecting projects.[226]

The TKDL has some limitations that future initiatives to codify TMK should attempt to minimize. A core limitation is that the database does not take a holistic approach in the way previously proposed. The information documented in the TKDL outlines only the types and amount of ingredients used in a resource for TMK in recipe format.[227] It disregards the cultural, historical, environmental, and geographic information that could be documented together with the knowledge.[228] As stated above, the value of codified TMK increases with its breadth.[229] 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.

The other major limitation of the TKDL is that it is currently only being used defensively to help invalidate non-inventive patent applications or to limit the scope of patent claims.[230] Access is

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[225] *See*, *e.g.*, *supra* Section IV.C; *see also* WIPO *supra* note 211.

[226] Christina Lee, *AncientBiotics: A Medieval Remedy for Modern Day Superbugs?*, UNIV. OF NOTTINGHAM (March 2015), 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.

[227] *See, e.g.*, *supra* Section IV.C; *see also* TKDL, *supra* note 214.

[228] *Id*.

[229] *See* discussion *supra* Section IV.B.

[230] TKDL, *supra* note 42.

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.[231] India has entered into access agreements with the European Patent Organization (EPO), the German Patent and Trademark Office (DPMA), the United States Patent and Trademarks Office (USPTO), the United Kingdom Intellectual Property Office (IPO), the Canadian Intellectual Property Office (CIPO),[232] Intellectual Property Australia (IP Australia), the Japanese Patent Office (JPO), the Indian Patent Office (CGPDTM), and the Chilean Patent Office (INAPI).[233] There are slight differences in the restrictiveness of each access agreement.[234] 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

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[231] *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 (on file with author).

[232] 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 "only to the extent that it is necessary for patent search and examination." 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 with the TKDL licenses. Traditional Knowledge Digital Library (TKDL) Access Agreement (with the United States Patent and Trademark Office) art. 2 (1) - Responsibilities and Obligations of USPTO.

[233] *Major Milestones*, TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL), http://www.tkdl.res.in/tkdl/langdefault/Common/AboutTKDL.asp?GL=#History (last visited Nov. 5, 2017).

[234] Compare the wordings of the following agreements between the Indian Governments and the patent offices of the US, EU, and Japan TKDL Access Agreement, *supra* note 86.

> citations. Except as mentioned above, 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.[235]

The access agreement with the USPTO 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."[236] 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.[237] Despite these differences in restriction, the TKDL's orientation is defensive, and it has a goal of invalidating or limiting non-inventive patent applications.[238] 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.

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[235] Traditional Knowledge Digital Library (TKDL) Access Agreement, Eur.-India, 2 (i-iv) (on file with author).

[236] *Id*.

[237] *Composition for the Treatment of Diabetes Mellitus and Metabolic Syndrome*, USPTO (July 8, 2010), http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=/netahtml/PTO/srchnum.html&r=1&f=G&l=50&s1=20100173022.PGNR.

[238] TKDL, *supra* note 42.

V. 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).[239] The disclosure of the invention, even if made by the inventors, would put the invention in the prior art category, barring it from patentability.[240] Some jurisdictions recognize grace periods in which inventors are given a limited amount of time after the disclosure of the invention to apply for a patent.[241] A grace period gives an inventor a certain amount of time (usually between six to twelve months)[242] from the time of the first disclosure of the invention to apply for a patent without affecting the novelty of the disclosed invention.

Given 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.[243] In other words, should the TMK codified and disclosed by the applicant be used as 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, it could disincentivize 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

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[239] 35 U.S.C. § 102(a) (2012).

[240] *Id*.

[241] *See*, *e.g.*, 35 U.S.C. § 102(b)(1) (2012); Canadian Patent Act (*R.S.C., 1985, c. P-4*), §§ 28.2(1)(a), 28.2(1)(a), 28.3.

[242] Both the US and Canada provide a one year grace period. *See* Canadian Patent Act (R.S.C., 1985, c. P-4), §§ 28.2(1)(a), Paragraphs 28.2(1)(a), 28.3, http://www.laws-lois.justice.gc.ca/eng/acts/P-4/; 35 U.S.C. § 102(b)(1) (2012).

[243] 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.

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.

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 a head start or 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 holders to invest in codifying and disclosing TMK. However, since the lead time would probably be an insufficient 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 a greater capacity for encouraging disclosure than a system in which the applicant would be submitting evidence that could prevent a subsequent patent application. The second system is advocated in this article. Since investments in the documentation and disclosure of TMK are expected to have significant risks, policy makers may need to provide a strong signal to TK-holder communities and licensees to invest in codification and disclosure, 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 adapted 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.

VI. BUILDING STAKEHOLDER BUY-IN

Another important challenge the proposed system will face is convincing the various stakeholders to agree to the framework. First, the proposed system must earn the source community's trust. Second, it must build confidence among bioprospectors to invest in the codification, disclosure, and use of TMK. And lastly, it must convince governments to establish the legal framework and support codification.

In many countries around the world, indigenous and local communities have been, and in many cases continue to be, oppressed culturally, politically, and economically.[244] Past experiences have forced many communities to be suspicious of outsiders, often 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. 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 successfully 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 regarding 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 a proposed licensing agreement to be insufficient. Terms and conditions of a licensing agreement can include economic and non-economic benefits or obligations. While communities that seek

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[244] *State of the World's Indigenous Peoples*, U.N. ECON. & SOC. AFF. (2009), http://www.un.org/esa/socdev/unpfii/documents/SOWIP/en/SOWIP_web.pdf; *see also* M. Annette Jaimes, THE STATE OF NATIVE AMERICA: GENOCIDE, COLONIZATION, AND RESISTANCE (RACE & RESISTANCE SERIES) (1992).

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.

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 source 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 central issue for users is why user-countries would agree to set up a legal framework that would further restrict the ability of persons within their jurisdiction to access TMK. The troubling protectionist trend in which TK holders are increasingly becoming restrictive in terms of granting access to their knowledge may be what encourages user-countries to buy into the framework. The current practice of gaining access to TMK without sharing any benefits with the knowledge providing communities does not seem to be sustainable in the long term. Provider countries and communities have already started restricting access to their knowledge because of the lack of protection.[245] The protectionist trend (and the potential for increasing restrictions on access to TMK) should encourage users—and, more importantly, their

[245] Carvalho, *supra* note 33, 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 4, at 757–65 (outlining national legislations enacted to protect TK in India, Brazil, Peru, The Philippines, and the Africa model legislation).

governments—to agree to shift to a system that rewards knowledge holders.

Even if users could evade these restrictions and access TMK, it might increase the cost of future access to the knowledge since knowledge holders will try to further restrict access. 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 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.

VII. CONCLUSION

After providing some introductory concepts about TK, this article situated TK in the public goods literature. Doing so allowed for the established economic concepts regarding public goods to be applied in examining alternative governance frameworks for TK. This article assessed the potential benefits and limitations of four of the common channels used in supporting investments in the production of knowledge goods in general in the context of TK. Each alternative framework has advantages and disadvantages, and a combination of these channels seems to be the more suitable approach for addressing the complex interests and scenarios present in the attempt to encourage investment in TK codification and disclosure.

In the case of "modern" knowledge, the recognition of private rights plays a key role in encouraging investments in knowledge generation and distribution. Following from this understanding, the recognition of private rights as an alternative legal framework for TMK codification and disclosure is outlined. It outlines the features of a bioprospecting right that balances the interests of the 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 publicly accessible databases or in restricted databases to which

a government agency or other entity would have access. The article 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. This option 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 because it may encourage source communities to over claim. The second alternative is the recognition of a right to share benefits from bioprospecting projects conducted by others. This second alternative, which only grants rights to share profits, involves lesser incentives to over claim and may encourage users to engage in bioprospecting projects with fewer transaction costs. While policy makers are encouraged to adopt a suitable framework for their jurisdiction, the second framework is preferred in this article. The transaction cost of using TMK in bioprospecting projects is lower in the second alternative since users are not required to negotiate with source communities *ex ante*, while source communities would still be able to share from the resulting profits.

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

While a specific term of these rights has not been provided, this article examined the key factors that policy makers should consider in designing the scope of the right. These include existing terms for intellectual property rights, database protection, and *domaine public payant*. Furthermore, the article also provided a hypothetical and actual example of TMK codification to help policy makers craft an appropriate protection regime. The establishment of a holistic codification that includes the details of TMK and its socio-cultural environment should be encouraged. The article concludes by examining the implications of TK codification and disclosure on subsequent patent applications and ways in which the

bioprospecting right could build the interests of diverse stakeholders.

A carefully crafted bioprospecting right will facilitate partnerships between source communities and users, thereby creating a more efficient and sustainable bioprospecting industry. Furthermore, the legal framework has the potential to save considerable TMK from loss through codification and disclosure. As a result, there are strong welfare-enhancing outcomes that can be expected from the establishment of an effective system of protection for TMK.