



January 2017

Traditional Knowledge in the Time of Neo-Liberalism: Access and Benefit-Sharing Regimes in India and Bhutan

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Recommended Citation

Barpujari, I., Sarma, U. K. (2017). Traditional Knowledge in the Time of Neo-Liberalism: Access and Benefit-Sharing Regimes in India and Bhutan. *The International Indigenous Policy Journal*, 8(1). DOI: 10.18584/iipj.2017.8.1.3

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Abstract

In a neoliberal world, traditional knowledge (TK) of biodiversity possessed by Indigenous and Local Communities (ILCs) in the global South has become a valuable "commodity" or "bio-resource," necessitating the setting up of harmonized ground rules (international and national) in the form of an access and benefit-sharing regime to facilitate its exchange in the world market. Despite criticisms that a regime with a neo-liberal orientation is antithetical to the normative ethos of ILCs, it could also offer a chance for developing countries and ILCs to generate revenue for socioeconomic development—to which they are gradually becoming open, but only under fair and equitable terms. Based on this context, this article proposes to look into the legal and policy frameworks and institutional regimes governing access and benefit sharing of TK associated with biological resources in two countries of South Asia: India and Bhutan. The article seeks to examine how such regimes are reconciling the imperatives of a neo-liberal economy with providing a just and equitable framework for ILCs and TK holders, which is truly participatory and not top-down.

Keywords

traditional knowledge, biodiversity, neo-liberalism, access and benefit sharing, India, Bhutan

Acknowledgments

The authors are indebted to the editor and independent reviewers for their comments and suggestions.

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Traditional Knowledge in the Time of Neo-Liberalism: Access and Benefit-Sharing Regimes in India and Bhutan

Traditional knowledge (TK) of biodiversity possessed by Indigenous and Local Communities (ILCs) in the global South has been generated and nurtured in the context of a deep, symbiotic interrelationship with the environment and sustained over generations in an ethos of sharing. This TK is holistic in nature and has intrinsic value—social, spiritual, economic, intellectual, scientific, ecological, technological, educational, and cultural—for ILCs (World Intellectual Property Organization [WIPO], 2014). Also, as a general rule, TK is communally held, barring instances of specialised knowledge, with customary laws generally not operating on the logic of exclusion (Dutfield, 2006). With increasing realisation of the economic potential of TK (for instance, as valuable leads to modern pharmaceutical companies), this TK finds itself in a neoliberal world order as a valuable “commodity” or “bio-resource.” This necessitates the setting up of harmonized ground rules (international and national) in the form of an access and benefit-sharing (also called ABS) regime to facilitate its exchange in the world market as well as to ensure that this exchange is based on just and equitable terms and that TK is not misappropriated.

Neoliberalism, as defined by Harvey (2005), is “a theory of political economic practices that proposes that human well-being can best be advanced by liberating individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets and free trade” (p. 2). The role of the state, according to Harvey, is to create and preserve an institutional framework appropriate to such practices; in other words, it establishes a rule of law that can protect and enforce contracts between juridical individuals in the marketplace. Neoliberalism also makes a strong case for regulating international trade as a means of safeguarding the same kind of commercial liberty and strong property rights that ought to be realised at the national level (Thorsen & Lie, 2009). As Saad-Filho and Johnston (2005) observed, “we live in the age of neoliberalism,” with neoliberalism being “the dominant ideology shaping our world today,” which as a hegemonic discourse has pervaded all aspects of human life, including TK generated in an entirely different life-world (p. 1). This is expected considering that neoliberalism is characterised by “the consistent expansion of the economic form to apply to the social sphere . . . transpose economic analytical schemata and criteria for economic decision making onto spheres which are not, or certainly not exclusively, economic areas” (Lemke, 2001, p. 197). A prominent example involves efforts to assign a monetary value to the services rendered by nature (ecosystem services) and using it as a tool for ensuring conservation, which is in sharp contrast with many Indigenous People’s deep sense of oneness and kinship with the natural world that has ensured its preservation. Similarly, such incongruence occurs when market values are imposed on TK, which is priceless, usually held collectively, and generated in “simple societies,” subscribing to a very different worldview and rationality than that of profitmaking.

One of the primary critiques of such commodification has been posed by Polanyi (2001) who contests the ethical correctness in putting a price on something that is priceless or whose value is more than merely monetary, which, in his view, produces fictitious commodities. This also leads to, in the words of Robertson (2004), “a successful attempt by capital to colonize and dominate the rationalities of other systems, with which it articulates” (p. 371). Further, the promise of socioeconomic development, which is the standard bait for participation in the neoliberal regime, remains unrealized in most instances (Castree, 2010). In addition, under neoliberalism, individuals are expected to be autonomous entrepreneurs (Lemke, 2001) who are solely responsible for the consequences of their action. Instances

of inequality and social injustice are morally acceptable, at least to the degree to which they could be seen as the result of freely made decisions (Thorsen & Lie, 2009).

In the particular context of TK, critics point out that neoliberal access and benefit-sharing regimes focussed on commodifying nature by making resources and associated TK tradeable through bilateral contracts is antithetical to the normative ethos of the ILCs (Nijjar, 2013). It also poses challenges for the non-Western others who seek to protect alternative forms of creative world making from appropriations and exploitations in Western commodity markets (Coombe, 2003). At the same time, the inevitability of participation in such a regime is bolstered by the neoliberal argument that the global South has many “unpriced” and often un-owned biophysical assets that, if inserted into global markets, could create revenue that would be able to support much needed socioeconomic development (Castree, 2010). As we shall see later on, countries like India and Bhutan are increasingly being persuaded by this logic with ILCs and TK holders in these countries becoming increasingly open to the idea of putting their TK in the market economy, but seek to do so under fair and equitable terms. Also, famous instances of biopiracy like that of basmati, neem, and ayahuasca¹ made developing countries and ILCs realise the imperativeness of protecting TK from misappropriation under the harmonized (Trade-Related Aspects of Intellectual Property Rights [TRIPS] Secretariat, 2002). In fact, the hegemonic overtones of the neoliberal regime have been continually countered and shaped through the participation of developing countries and ILCs in meetings under the Convention on Biological Diversity (CBD), the TRIPS Council, and WIPO. It is here that they have fought hard to incorporate justice, equity, and accountability in the international structure, while simultaneously contributing to the creation of innovative regimes of access and use of TK at local, regional, and national levels (Coombe, 2003).

It is against this backdrop that this article proposes to look at the legal and policy framework and institutional regimes governing access and benefit sharing of TK associated with biological resources in the two countries of South Asia—India and Bhutan. In this article, we seek to study this in the context of the international regime on access and benefit sharing, which provides a broad template for national regimes (which is usual in a neoliberal framework). The scope of this article extends to the intellectual property rights (also called IPR) regime as well to the extent of its overlap and linkage with the access and benefit-sharing regime. The provisions of intellectual property rights, particularly the patent regime, can have a considerable bearing on the effectiveness of the access and benefit-sharing regime in

¹ Biopiracy refers to the practice in which others (usually by biopharmaceutical companies) use TK for profit without permission from the TK holders and the country from which the resource is sourced, and without any sharing of the benefits. For instance, Indian communities and farmers have known about and used the neem tree for its fungicidal properties for a very long time. Based on this TK, which was in the public domain (and was accessed without prior informed consent or a benefit-sharing agreement), a patent was granted by the European Patent Office to a U.S. Corporation for a method of controlling fungal diseases using neem oil extract. An opposition was filed by a group of international non-governmental organizations (NGOs) and representatives of Indian farmers and this patent was subsequently revoked. India also decided to step up protection for TK in its national laws. Similarly, in the case of ayahuasca, the knowledge of the shamans of the Amazon basin on the medicinal properties of the plant was patented in the U.S. and was opposed by representatives of Indigenous tribes in the region. Unfortunately, this opposition did not prevail, resulting in manifest injustice to TK and ILCs. Such instances have advanced the case for establishing an access and benefit-sharing regime at the international and national levels, which would enable access to the TK while also ensuring that prior informed consent and benefit sharing are enforced.

preventing misappropriation. For example, if the requirements of prior informed consent (called PIC) and benefit sharing in the access and benefit-sharing regime are backed by provisions in patent law that require documentation of these in cases involving TK and in their absence the patent can be opposed or revoked then protections are strengthened significantly. Out of eight countries in South Asia, only these two—India and Bhutan—have enacted laws and put in place a policy and institutional framework in tune with their international commitments on access and benefit sharing. These international commitments include the CBD (United Nations, 1992), and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization negotiated within it (Secretariat of the Convention on Biological Diversity, 2010). For this reason, we focus on India and Bhutan (though extremely disparate in terms of size and institutional arrangements) as representative cases of access and benefit-sharing mechanisms in South Asia. Both the countries have also been engaged in revising their legal and policy frameworks to ensure conformity to the same.

A primary focus of this article is to examine how India and Bhutan, through their national policy and legal frameworks, are reconciling the imperatives of a neoliberal economy with the need for a just and equitable framework for ILCs and TK holders, which is truly participatory and not top-down. This article also attempts to provide recommendations for ensuring adequate protections.

This article is largely based on an analysis of relevant policies and laws at the international level as well in the context of the countries of India and Bhutan. This analysis is supplemented by interviews with key stakeholders and the incorporation of Indigenous perspectives and efforts to the extent that this is feasible.

The International Regime on Access and Benefit Sharing and its Relationship with the TRIPS Agreement

There is a growing realization, embodied in policy and scientific recommendations, of the tremendous value of biological diversity to present and future human generations. There is also cognizance of the human induced threats that underlie the United Nations Environment Programme's (UNEP) decision to create the Ad Hoc Working Group of Legal and Technical Experts in the mid-1990s. This group prepared a new international legal instrument for the conservation and sustainable use of biological diversity, which took the form of the CBD in 1992 (CBD, 2007). It was mandated to take "particular account of the need to share costs and benefits between developed and developing countries and ways and means to support innovation by local people" (CBD, 2007). Before the CBD, "common heritage of mankind" was the international principle with respect to genetic resources, which allowed them to be extracted and used with impunity to the detriment of developing countries in the South that possessed the most biodiversity in the world. The CBD (UN, 1992) tried to make amends with these countries by doing away with the earlier principle and recognizing the sovereign right of countries over genetic resources within their jurisdiction and also recognizing the role of ILCs in preserving the same and the need to share benefits when their TK associated with genetic resources was utilized.

The CBD constitutes the primary international agreement in the world today on biological diversity, with the avowed objectives of its conservation, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (UN, 1992, Article 1).

In recognition of the critical role of ILCs in biodiversity conservation, Article 8(j) of the Convention enjoins each contracting party, subject to its national legislation, to:

Respect, preserve and maintain knowledge, innovations and practices of ILCs embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Article 15 recognizes the sovereign rights of states over their natural resources, granting them the authority to determine access subject to prior and informed consent with a duty on contracting parties to take steps to ensure the fair and equitable sharing of benefits arising from the commercialization or utilization, based upon mutually agreed terms.

While primarily being an environmental agreement, as Coombe (2003) observed, the CBD partakes in neoliberal logic with biological resources being represented as goods that are most appropriately dealt with in an open system of flows, which need to be efficiently mapped, monitored, and transferred so that information about genetic resources can be globally cumulated, communicated, and, most importantly, capitalized upon. The recognition of the role of ILCs is also attributed to the neoliberal interest of better management of biological resources. This includes ensuring the juridical conditions required for contractual relations involving their use and attempting to balance the desire to access to resources, which stems primarily from the global North, with rights concerning the use of knowledge, prior and informed consent, and the sharing of benefits, which predominantly affect those in the global South (Coombe, 2003). Despite its lofty ideals, the CBD (UN, 1992) has also been subject to much criticism owing to a number of weaknesses that are perceived to dilute the provisions that are favourable to ILCs. In particular, there is the issue of whether the CBD mandates prior and informed consent and benefit sharing with respect to TK or whether these requirements are only applicable with respect to biological resources. There is also concern around the concentration of rights at the state level, which allows them to grant access (including on behalf of ILCs) to third parties under Article 15. Finally, there is the perceived ineffectiveness and lack of implementation of the access and benefit-sharing regime (Koutouki & von Bieberstein, 2012; Nijar, 2013). There has been a lot of debate about whether parties are obligated to make prior and informed consent from ILCs a requirement of access to TK. In response to this concern, the fifth meeting of the Conference of Parties in 2000 established a general principle that access to TK should be subject to the prior and informed consent from its holders (Nijar, 2010). Further, several years into the CBD, there was hardly any effective access and benefit-sharing regime owing to the failure of user states to introduce their own benefit-sharing regimes, which compelled provider states to have extremely restrictive regimes as the latter remained the sole tool to prevent rampant biopiracy (Kamau, Fedder, & Winter, 2010). All of these concerns provided the thrust for the Conference of the Parties (COP) to create the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (or WG-ABS) at its fifth meeting, held in 2000 at Nairobi (Decision V/26) (COP, 2000). The Working Group was given the mandate to develop guidelines and other approaches for implementing access and benefit sharing. Accordingly, the Working Group came out with the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Secretariat of the Convention on Biological Diversity, 2002), which was adopted unanimously by 180 countries. As the term “guidelines” indicates, these are voluntary but do constitute

the first widely accepted criteria on access and benefit sharing. Later, the mandate of the Working Group was extended, in collaboration with the Working Group on Article 8(j) and Related Provisions.² This mandate aimed to elaborate on and negotiate an international regime with the aim of adopting an instrument or instruments to effectively implement the provisions of Articles 15 and 8(j) and the three objectives of the CBD (COP decision VII/19 at the Seventh COP held in Kuala Lumpur in 2004) (COP, 2004). On October 29, 2010, after 6 years of negotiation, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted at the tenth meeting of the Conference of the Parties in Nagoya, Japan. It came into force on October 12, 2014 (CBD, n.d.b).

The seminal provision of the Protocol with respect to TK associated with genetic resources is Article 7, which provides that:

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by Indigenous and Local Communities is accessed with the prior and informed consent or approval and involvement of these Indigenous and Local Communities, and that mutually agreed terms have been established. (Secretariat of the CBD, 2010)

Article 12(1) enjoins that:

Parties shall, in accordance with domestic law, take into consideration Indigenous and Local Communities' customary laws, community protocols and procedures, as applicable. (Secretariat of the CBD, 2010)

As per Article 12(3), Parties are to support, as appropriate, the development of the following by ILCs, including women within these communities:

- a. Community protocols in relation to access to TK associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
- b. Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of TK associated with genetic resources; and
- c. Model contractual clauses for benefit sharing arising from the utilization of TK associated with genetic resources. (Secretariat of the CBD, 2010)

While the Nagoya Protocol has been hailed for its achievement in finally putting in place a “binding” regime on access and benefit sharing internationally with enhanced rights of ILCs over their TK, it has

² The CBD, particularly the Ad Hoc Open-Ended Working Group on Article 8(j) and Related Provisions, has set up mechanisms to ensure full and effective participation of ILCs in meetings held under the Convention. These provision range from financial support to enable ILCs to attend the meetings, to logistical support, as well as participation in formal and informal groups (such as contact groups and Friends of the Chair groups). ILC representatives who attend meetings held under the Convention form a caucus that is referred to as the International Indigenous Forum on Biodiversity (CBD, n.d.a).

been criticized chiefly for its use of debilitating qualifiers (e.g., “as appropriate,” “where applicable,” “as far as possible”) and weak language (e.g., “endeavour,” “encourage,” “consider,” and “promote”), which creates room for legal ambiguity and uncertainty (Kamau et al., 2010). In addition, despite efforts to the contrary, the Protocol, much like the CBD, continues to accord priority to state sovereignty over the rights of Indigenous People, which severs the all-important connection between community and biodiversity to the detriment of both (Koutouki & von Bieberstein, 2012). The rights bestowed upon ILCs over TK and its access (Secretariat of the CBD, 2010, see Articles 7 & 12) are considerably watered down by the repeated stress on “in accordance with domestic law” and “as appropriate.” As per Article 12(1), Parties are to take into account customary laws only in accordance with domestic law (Secretariat of the CBD, 2010). Also, the Protocol is silent over the question of intellectual property rights of ILCs related to their TK. Interestingly, the Protocol, in its preamble, makes cognizant note of the provisions of the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) (UN, 2007), which was adopted by the General Assembly of the United Nations in 2007. A number of provisions in UNDRIP (2007)³ read and interpreted together provide a positive rights regime for ILCs with respect to their TK in the sense that the rights flow from their ownership of their TK and are not contingent or dependant on the state (which is the case, as discussed above in the CBD and Nagoya Protocol). However, UNDRIP, adopted by means of a UN General Assembly Resolution, is “soft” law that is non-binding in nature and hence has limited potential to affect state behaviour (Barelli, 2009).

It would also be pertinent to discuss the interaction between the access and benefit-sharing regime and the TRIPS Agreement (World Trade Organization [WTO], 1994), which is critical to the protection of TK from misappropriation. The TRIPS Agreement enacted within the framework of the WTO lays down minimum standards of intellectual property rights protection in WTO member countries and is the single most important international treaty on intellectual property rights today. TRIPS does not deal with TK *per se*, but its provisions—particularly those dealing with patents—have a considerable bearing on the protection of TK. The TRIPS Agreement creates an obligation among WTO members to provide patents for any invention, whether a product or a process, in all fields of technology based on three patentability criteria: novelty, non-obviousness or inventive step, and industrial application (WTO, 1994). With most TK having been in existence for a long time, publicly known, and handed down from generation to generation, it fails to satisfy the criteria of novelty required by TRIPS, which in turn facilitates its use as “prior art.” Since the Agreement does not recognize any intellectual property rights over TK, the laws of many developed nations permit the patenting of inventions based on these (amounting to biopiracy); thus, misappropriating the TK of ILCs in developing countries. The manifest injustice of the situation has prompted developing countries to lead the campaign to amend the

³ Article 31(1) of UNDRIP strongly affirms the rights of Indigenous Peoples to:

Maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. (UN, 2007)

It also recognizes upfront their right to maintain, control, protect, and develop their intellectual property rights over the same.

Agreement to achieve harmonization with the objectives of the CBD.⁴ They have also sought to incorporate provisions preventing the patenting of inventions based on TK and strong disclosure requirements (with respect to inventions based on biological resources and associated TK) within TRIPS to prevent misappropriation of TK (Submission by Brazil, India, China and others at the TRIPS Council, 2002; Submission by Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru, and Venezuela to the TRIPS Council, 2003). However, despite the mandate of the Doha Ministerial Declaration (2001) requiring the TRIPS Council to look into the relationship between the TRIPS Agreement, the CBD, and the protection of TK, the matter continues to be opposed by many developed countries at the TRIPS Council. As a result, this issue remains unresolved and negotiations have been deadlocked (WTO General Council, 2008). Following the Nagoya Protocol, a new proposal was submitted led by Brazil, China, India, and other countries (Trade Negotiations Committee, WTO, 2011). This proposal focused on achieving mutual support among TRIPS, the CBD, and the Nagoya Protocol through the incorporation of a new Article 29bis in the TRIPS Agreement. Member states would require patent applicants to disclose the origin of genetic resources and associated TK as well as evidence of compliance with the national access and benefit-sharing legislation of the provider country. However, to date, no breakthrough has come about; this diminishes the positive gains from the Nagoya Protocol since the TRIPS Agreement has greater influence, owing to its strong dispute settlement mechanism and capacity to impose trade sanctions.

The mismatch between the intellectual property rights regime designed to protect private rights and the nature of TK has also led the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGRTKF), set up by WIPO, and the Working Group on Access and Benefit Sharing of the CBD to contemplate the possibility of a *sui generis* regime. It would be designed especially for the protection of TK while borrowing compatible elements available in existing mechanisms of intellectual property rights protection (CBD, 2007; WIPO, 2002). However, not much headway has been made in this direction.

Access and Benefit-Sharing Regimes in South Asia: The Case of India and Bhutan

India

India is a mega-diverse country with over 91,200 species of animals and 45,500 species of plants documented in its 10 bio-geographic regions (Ministry of Environment and Forests, Government of India, 2014). It is also a vast repository of TK associated with biological resources and has a huge population that is dependent on it. India has been the forerunner in the South Asia region in enacting and implementing an access and benefit-sharing regime for biological resources and associated TK in the form of the Biological Diversity Act and the rules made thereunder in 2004 (National Biodiversity Authority, India, 2002, 2004), which are in line with the mandate of the CBD. The Biological Diversity Act lays down the institutional structure as well as procedures governing access to biological diversity

⁴ Article 16(5) of the CBD recognises that intellectual property rights, the subject matter of the TRIPS Agreement, “may have an influence on the implementation” of the CBD (UN, 1992). It obliges states to cooperate in order to ensure that intellectual property rights are “supportive of and do not run counter to” the objectives of the CBD (UN, 1992).

and the associated knowledge. The Act provides a three tier decision-making structure: the National Biodiversity Authority (NBA) at the centre, the State Biodiversity Boards (SBBs) at the state (sub-national) level, and the Biodiversity Management Committees (BMCs) at the local level (National Biodiversity Authority, India, 2002). Chapter II of the Act requires approval from the NBA for commercial or scientific requests for use of biological resources by foreigners as well as all applications for intellectual property rights on biological resources and associated TK.⁵ The SBBs are empowered under Section 23 to grant approvals for commercial or scientific use of biological resources by Indians. Section 41 of the Act mandates that local bodies (panchayats and municipalities) establish Biodiversity Management Committees (BMCs) in their area. The NBA and SBA are required to “consult” with BMCs while making any decision related to the use of biological resources and associated TK occurring within their territorial jurisdiction, with BMCs also empowered to levy collection fees from any person collecting or accessing any biological resource for commercial purpose in their area (National Biodiversity Authority, India, 2002). The Biological Diversity Rules (National Biodiversity Authority, India, 2004) provide for the constitution of the BMC, which consists of a chairperson and not more than six persons nominated by the local body, of whom not less than one third should be women and not less than 18% should belong to the Scheduled Castes and Scheduled Tribes.⁶ The main function of the BMC (Rule 22.6) is preparation of the People’s Biodiversity Register (PBR), which shall contain comprehensive information on availability and knowledge of local biological resources, their medicinal or other uses, as well as any other TK associated with them, in consultation with the local people (National Biodiversity Authority, India, 2004).

Section 21—which provides the procedure for benefit sharing—confers the main authority to the NBA though it is mandated to consider the mutually agreed terms and conditions between the person applying for approval, concerned local bodies, and the benefit claimers. This authority is further reinforced by section 2(g), which defines fair and equitable benefit sharing as “sharing of benefits as determined by the National Biodiversity Authority (NBA) under Section 21.” Section 6(2) further states that the NBA may impose a benefit-sharing fee or royalty, or both in granting the approval (National Biodiversity Authority, India, 2004).

From the above discussion, it emerges that despite the provision for a decentralised structure, the power to regulate access and benefit sharing is concentrated mainly in the NBA, though the former is mandated to “consult” the local body (the BMC), thus depriving it of an equal stake in the access and benefit-sharing negotiations. The Act is also conspicuously silent about the actual right of knowledge holders over the question of access by a third party. Further, the reduction of the role of the local body to mere

⁵ This provision is diluted by the absence of a similar provision in the Patents (Amendment) Act (India) (2005), which is the primary national legislation governing patents. However, the Guidelines for the Processing of Patent Applications Relating to Traditional Knowledge and Biological Material (2012) seek to address this shortcoming. They provide guidelines for better coordination between the Patent Office and the NBA in dealing with patents related to biological resources and associated TK. TK is *per se* not patentable under the Indian patent legislation, which has a disclosure requirement with respect to source or geographical origin of biological material used in the patent application. Applicants must also disclose whether the invention or any claim under it is rooted in TK, oral or otherwise. Non-compliance to these provisions is grounds for opposition and revocation of the patent (see Section 25).

⁶ The Scheduled Castes (SCs) and Scheduled Tribes (STs) are official designations given to various groups of historically disadvantaged Indigenous Peoples in India who are recognized in the Constitution of India.

documentation of its biological resources and associated TK, without corresponding ownership and control over the same has been subject to much criticism due to its hegemonic character and is perceived as “a sell out to bio-based trade at its best” (Kohli, 2006). In fact, a protest was organised by approximately 300 representatives of panchayats and gram sabhas,⁷ supported by non-governmental organizations (NGOs) and citizens’ groups on December 8, 2004, to protest against the Rules. In 2007, resolutions from more than 3,000 gram panchayats, local institutions, and community organisations were sent to the prime minister, reiterating their refusal to form BMCs unless certain prerequisites for ensuring control by the people, recognition of their rights, and legal protection for PBRs were met (Kohli & Bhutani, 2014).

Partly in response to these demands, the NBA brought out the Guidelines for Operationalization of BMCs in 2013, which required the involvement of tribal groups and other marginalised groups in the process of BMC formation. The Guidelines also sought to expand the role and functions of the BMCs, apart from preparation of PBRs, to include:

- a. Protecting the TK recorded in the PBR; providing feedback to the SBB (as well as the NBA) in matters related to intellectual property rights, TK, and local biodiversity use;
- b. Regulating of access to biological resources and associated TK for commercial and research purposes;
- c. Ensuring sustainable use and benefit sharing; and
- d. Documenting and enabling procedures for developing bio-cultural protocols.

In addition, the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit-Sharing Regulations (National Biodiversity Authority, India, 2014) were also brought out as a piece of secondary legislation under the Biodiversity Act (National Biodiversity Authority, India, 2002). The Guidelines are to be commended for trying to make it so 95% of the accrued benefits, monetary and/or non-monetary, are passed on to concerned BMC(s) and/or benefit claimers (National Biodiversity Authority, India, 2014). These also recognize the claims of individuals, groups of individuals, or organisations from whom the biological resource or knowledge is sourced, providing for the direct transfer of the benefits received to the appropriate individual, group, or organisation. While continuing to reinforce the primary role of the NBA, the Rules provide a space, albeit a limited one, for participation of BMCs through the SBBS in whose jurisdiction the biological resources and the associated knowledge occur during the NBA’s decision-making on a related application.

Thus, it emerges that, owing to pressure from local bodies and communities, the Biodiversity Act, while retaining the primary role of the centralised NBA, is gradually moving towards more participation at the local level. However, the fact that these pro-people changes have been implemented through guidelines rather than through amendments in the main legislation itself weakens their legal enforceability. At the same time, there is a serious omission in these new Guidelines, which were intended to give effect to the requirements of the Nagoya Protocol. There is the lack of recognition given to bio-cultural protocols,

⁷ Local bodies under the Panchayati Raj system of local governance constituted through the 73rd amendment to the Constitution of India.

which serve as the primary tool for ILCs to lay down their terms for access and benefit sharing in sync with their customary laws and institutions (National Biodiversity Authority, India, 2014). Here, it may be mentioned that different ILCs from different parts of India (for example, the Baigas of Chattisgarh, the Monpas of Arunachal Pradesh, the Danus and Takuli of Uttarakhand) with support from the United Nations Development Fund (UNDP) have prepared about 12 BCPs that are intended to be linked to the PBRs, but as of yet have no legal enforceability. A reading of the BCPs makes evident that, while ILCs continue to treat TK—their ancestors' knowledge—as sacrosanct, they understand that the modern regime necessitates sharing their knowledge. They are prepared to share their knowledge “on the basis of care for nature and reciprocity that must include benefit sharing” (Monpas of Salari, n.d., p. 6). The Baigas of Tatidhar village (n.d.) asserted, “we do not distrust outsiders . . . however, we have learnt about the many incidents and experiences in our country and other countries where tribal people have suffered” (p. 10). For this reason, they want outside agencies and individuals to seek their consent before accessing their knowledge or their plants. ILCs are also concerned about restrictions on their access to the forests, which are vital to their TK. The increasing lack of interest among youth and illegal extraction by outsiders are areas of concern. The authors' own research among the members of the Karbi tribe of Assam shows that there are marked intergenerational differences within the same community regarding perceptions about knowledge, knowledge sharing, and intellectual property rights (Sarma & Barpujari, 2012). The study found that the younger generation, particularly educated youths, exhibit less reverence for the TK of the tribe and tended to dismiss many Indigenous-healing practices as superstitions. However, ironically, they displayed considerable enthusiasm for the potential commercialization of this knowledge and for the idea of intellectual property rights and benefit sharing. On the other hand, the older generation, particularly those possessing specialist knowledge, expressed reluctance to share the knowledge because it is embedded within the socio-religious beliefs of the community and they feel an allegiance to its traditional ethos, which permits its use only for the welfare of the society and not for profit.

Turning to the implementation of the institutional mechanism after almost 14 years under the Biological Diversity Act, current reports present a dismal picture: Among 15 states surveyed, only 16% of the local bodies have constituted BMCs, while less than 3% of the local bodies have prepared PBRs (Shrivastava, 2016). As far as access and benefit-sharing arrangements are concerned, while about 408 approvals have been sanctioned (National Biodiversity Authority, India, 2017), there have been very few instances of benefit sharing with BMCs, which has been mostly with respect to extraction of biological resources for which one-time payment has been made to the respective BMCs (Kohli & Bhutani, 2014). Data from the NBA indicates that monetary benefits have been minimal; for instance, between 2011 and 2012, the NBA received only Rs 1,98,603 (a very small amount) in royalties from access applicants (Kohli & Bhutani, 2015).

Bhutan

Bhutan is a small landlocked country between India and China in the eastern Himalayas recognized as a global biological hot spot. It has about 300 species of medicinal plants found at different altitudes for which the Himalayan kingdom has been referred to as Lhomenjong or the valley of medicinal plants. These plants have been nurtured by local custodians motivated by “strong spiritual and cultural bonds with their local ecosystems” (Ministry of Agriculture and Forests, Royal Government of Bhutan, 2014, p. 2). Conservation of biological diversity has always been an integral part of Bhutan's national policy

framework, with the protection of the country's natural resources and environment mandated in the Constitution of the Kingdom of Bhutan, which also recognizes the trusteeship of the Bhutanese citizens over the same (Royal Government of Bhutan, 2008, Article 5). At the same time, the country has been very amenable to the neoliberal idea of exploiting its biological resources as "a development capital for national economic growth but within the limits of environmental sustainability" (Ministry of Agriculture, Royal Government of Bhutan, 2009, p. 89). It has sought to capitalise on its "rich biodiversity and widespread existence of traditional knowledge and practices among local communities" to embark on bioprospecting as "a potentially very lucrative conservation enterprise" (Ministry of Agriculture, Royal Government of Bhutan, 2009, p. 104). While recognizing the strong spiritual and cultural bonds of ILCs and TK holders with their local ecosystems and seeking to preserve them, Bhutan has been pragmatic in realizing that such bonds could become frayed due to growing economic pressures. To address this issue, the country's position has been to secure the economic value of biological resources and associated TK by facilitating research and commercial utilization, as well as ensuring fair and equitable sharing of benefits arising from such activities (Ministry of Agriculture and Forests, Royal Government of Bhutan, 2014).

Following the ratification of the CBD (UN, 1992) by Bhutan in 1995, the country enacted the Biodiversity Act of Bhutan. The Biodiversity Act of Bhutan, while asserting the national sovereignty of the Royal Government of Bhutan over its genetic resources among other objectives, also seeks to prevent illegal access to genetic resources and associated TK, as well as aiming to recognize and protect TK, innovations, and practices of local communities (Ministry of Agriculture, Royal Government of Bhutan, 2003, Section 2). The Act lays down procedures for securing access to associated TK, which involves obtaining prior and informed consent from the owners of TK in order to use TK for non-customary uses (Ministry of Agriculture, Royal Government of Bhutan, 2003, Section 37). The importance of prior and informed consent is further reinforced as the fundamental principle for access in the Preamble of the Act. The applications for access and the necessary permits are processed by the Authorised Agency (defined as the body designated as Authorised Agency by the Competent Authority under the Act). They are then submitted to the Competent Authority (defined in the Act as the Head of the Ministry of Agriculture, Royal Government of Bhutan) who may grant or refuse applications (Ministry of Agriculture, Royal Government of Bhutan, 2003, Chapter 2). A noteworthy provision is the primary right of TK holders to either accept or reject an application for access (under Section 38), though this right is not absolute because the competent national authority retains the final right to approve or deny the agreement based on national interests (Ministry of Agriculture, Royal Government of Bhutan, 2003, Section 39). Section 42 provides for the inventorisation and documentation of TK to be done by the authorized agency in collaboration with the owners of TK. In addition, under Section 35, owners under The Act (the TK holders) are to enjoy the right in perpetuity, applicable even if the TK is not in material form as outlined in Section 34 and as stated in Section 36. These rights are in addition to

and do not affect any rights that may subsist under any intellectual property rights laws⁸ (Ministry of Agriculture, Royal Government of Bhutan, 2003). Under Section 49, the onus is on the Competent Authority to formulate and adopt rules and regulations to implement the Act (Ministry of Agriculture, Royal Government of Bhutan, 2003).

Despite efforts over the years to draft rules and regulations in order to implement the Act—such as the Biodiversity Action Plan (Ministry of Agriculture, Royal Government of Bhutan, 2009)—even after 13 years, the Act presently stands unimplemented.⁹ However, even in the absence an act, Bhutan has had a functional access and benefit-sharing mechanism: the National Biodiversity Centre (NBC), which Bhutan instituted in 1998 under the Ministry of Agriculture and Forests. The NBC is the main implementing agency of the CBD. It is responsible for coordinating biodiversity conservation and sustainable use programs in the country. Its mandate extends, among other things, to serving as the national focal agency to regulate access to biological resources and ensure equitable sharing of the benefits. It is responsible for developing policies and legal frameworks for conservation and sustainable utilization of biological resources. It also serves as the national focal agency for bioprospecting and documentation of TK (National Biodiversity Centre, Bhutan, 2017). Here, it may be mentioned that in 2009 a bioprospecting division was launched under the aegis of NBC, Bhutan. It includes a Traditional Documentation Unit, a Bio-Exploration Unit, and a Research Unit. Its objective is to tap into genetic resources and associated TK within the country in order to contribute to the development of new and clean industries based on bioprospecting and genetic engineering. This innovation is expected to place Bhutan in the vanguard of scientific advancement for the benefit of humankind (Planning Commission, Royal Government of Bhutan, 2011). At the same time, the importance of traditional medicine¹⁰ has been upheld as an integral part of the public health services system. Traditional medicine units are attached to modern district hospitals and Basic Health Units (BHUs) that function under the guardianship of the Institute of Traditional Medicine Services (IITMS, Thimphu), which has now become the Department of Traditional Medicine Services under the Health Ministry. Menjong Sorig Pharmaceuticals, formerly the Pharmaceutical and Research Unit of IITMS, is engaged in the production of traditional medicine using about 300 medical plants from the wild in order to supply to all the hospitals of Bhutan. This process has involved communities in the sustainable collection and cultivation of medicinal plants from the wild (UNDP, 2014). The potential for bioprospecting on these

⁸ The primary intellectual property rights legislation of Bhutan is the Industrial Property Act of the Kingdom of Bhutan (2001). Under this Act, a patent is granted for an invention that is new, involves an inventive step, and is industrially applicable (Section 5(1)). While methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body are non-patentable (Section 4(3)(iii)), there is a proviso regarding its non-applicability to products for use in any of these methods. A broad inference can be drawn from these provisions—products based on TK are patentable in Bhutan and require no disclosure of the use of the TK.

⁹ In an interview with Dr. Tashi Yangzome Dorji, program director of the NBC in Bhutan, at Thimphu in June of 2012, we learnt that one of the reasons this legislation was kept on hold was that a draft access and benefit-sharing policy, in line with commitments under the Nagoya Protocol, was being formulated. It was therefore necessary to subsequently amend the legislation in line with the policy.

¹⁰ Bhutan is home to two forms of traditional medicines: local healing practices (mostly oral traditions) and the formalized traditional medical system known as gSo-ba-rig-pa medical system, which is highly sophisticated and fully documented (Wangchuk, 2008).

plants has highlighted the need for international collaboration in future research and production (Wangchuk, 2008).

In an interview with Dr. Tashi Yangzome Dorji, program director at NBC in Bhutan, at Thimphu on June 20, 2012, we learned that, until the Biodiversity Act is implemented, the NBC would continue to be the authorized agency responsible for receiving and approving applications for bioprospecting. When such a proposal is received, it is subject to scrutiny by a scientific review committee set up by the NBC. The scientific review committee is composed of experts from the Department of Agriculture, the Department of Forests and Park Services, the Department of Livestock, the Department of Agricultural Marketing and Cooperatives, the Policy and Planning Division of the Ministry of Agriculture and Forests, the Council for RNR Research of Bhutan, the Institute for Traditional Medicine Services, the Intellectual Property Division of the Ministry of Economic Affairs, and the NBC. Once an application is approved by the committee, final approval lies with the secretary of the Ministry of Agriculture and Environment. At the time of the interview, only two cases had been approved—one involved a private sector collaboration with the NBC, while in the other instance a company outside Bhutan collaborated with the government. The status in 2014 is not much different—three memoranda of agreement or understanding have been entered into with various private enterprises and an additional four proposals are in the early stages of consideration for potential access and benefit-sharing collaborations (UNDP, 2014).¹¹

Dr. Tashi Yangzome Dorji said that the Nagoya Protocol of 2010 provided a boost to policy making in the area (personal communication, June 20, 2012). Bhutan sought to firm up an access and benefit-sharing policy and it was considering its stated position on bioprospecting and commitments under the Protocol. The country has since firmed up the draft Access and Benefit-Sharing Policy of Bhutan, in which access to genetic resources and associated TK is divided into two phases—a scoping phase and an actualization phase—with different conditions for each phase (Ministry of Agriculture, Royal Government of Bhutan, 2014). Permission for the scoping phase is envisaged through a scoping permit or an agreement between the national focal point and the user, which lays down a set of conditions for utilization (including the condition to fulfill the requirements of the actualization phase prior to engaging in the actualization phase). It will be conditional on payment of a processing fee and a cash deposit that is returnable on conclusion of the scoping phase. The actualization phase requires:

- a. An actualization permit to be issued by the national focal point; and
- b. An access and benefit-sharing agreement between the users and the providers of genetic resources and/or associated TK.

¹¹ NBC has an access and benefit-sharing agreement with Bhutan Pharmaceutical Private Limited (BPPL), a private national company, on *Ophiocordyceps sinensis* and other insect fungi, while Nimura Genetic Solutions, Malaysia has so far invested approximately US\$300,000 for technology transfer related to research and development and collaborative research on Bhutanese star anise. NBC has also entered into a Memorandum of Agreement with an international company, Quantum Pharmaceuticals Limited (QPL), for sale of orchid (*Cymbidium erythraeum*) flowers as one of the ingredients for the production of a cosmetic product called REDEEM (UNDP, 2014).

The national focal point will provide oversight, where appropriate, over negotiations between the users and the providers in the access and benefit-sharing agreement. The access and benefit-sharing agreement may include both monetary and non-monetary benefits (Ministry of Agriculture, Royal Government of Bhutan, 2014).

Access to TK associated with biological resources (held by one community) will require an access and benefit-sharing agreement between the community based on their community protocol, with guidance from the national focal point and the user. Where TK is held by more than one community, an access and benefit-sharing agreement will be negotiated between the communities in accordance with their community protocols under the guidance of the national focal point and the user. Where this is not feasible, the national focal point shall enter into an access and benefit-sharing agreement on their behalf. The draft policy provides that monetary benefits derived from research and commercialization of genetic resources and/or associated TK (including the processing fee and the cash deposit payable at the scoping phase) is to be channelled to an access and benefit-sharing fund. This fund is managed by the national focal point, which shall disburse the funds for conservation and sustainable use of Bhutan's biodiversity and for the enhancement of rural livelihoods.

While the draft Access and Benefit-Sharing Policy is still pending final approval, a new Biodiversity Bill of Bhutan (2016) was added to the NBC website in March of 2016, which, as stated in the preamble itself, seeks to repeal the existing Biological Diversity Act of 2003. A reading of the Bill makes evident that its basic intention is to give legal teeth to the access and benefit-sharing mechanism envisaged in the draft Access and Benefit-Sharing Policy, such as the two kinds of access and benefit-sharing agreements, the creation of an access and benefit-sharing fund, etc. It also aims to provide the legal backing for the prevailing institutional arrangement with the NBC as the national focal point and the secretary of the Ministry of Agriculture as the competent national authority. However, what is striking is the concentration of all powers in the competent national authority and the national focal highlights the omission of communities and TK holders in the decision making process, which is a complete departure from the earlier Act and even the draft Access and Benefit-Sharing Policy. To illustrate this, one can take Section 26 on prior and informed consent, which specifies that access is subject to prior and informed consent of the competent national authority, which can seek prior and informed consent from the providers of genetic resources where it considers appropriate (proviso to Section 26). Further, Section 27 provides that the competent national authority may grant or refuse prior and informed consent based on the recommendations of the national focal point. This is a major deviation from the Biological Diversity Act of 2003, which gave communities the right to accept or reject an access application. It is indeed strange that while seeking to enact laws and policies to give effect to the Nagoya Protocol, which Bhutan ratified in 2013, the new Bill has a provision that goes against the fundamental principle of the Protocol ensuring the prior and informed consent of ILCs and TK holders. The only time the prior and informed consent of local communities and TK holders is mandatory is during the process of documenting TK by the national focal point, which is required to maintain a national TK database (Sections 61 & 62). The result is a situation where post-documentation ILCs and TK holders have no role in decision-making on the issue of access and benefit sharing, which becomes the prerogative of the state agencies. The Act casts a duty on the national focal point to support and promote communities in developing community protocols on TK associated with genetic resources (Section 64), but this is not backed by a requirement under the law to consult those communities while determining access and benefit sharing.

Now, if we are to look into the engagement of ILCs in the policy making process in Bhutan, a survey of existing literature seems to indicate a low level of engagement among ILCs in the actual policy making process (unlike in India where local bodies and communities have fought hard to make laws more participatory). This may be attributed to a lack of awareness about and absence of community mobilisation on the issue, stemming from the socioeconomic conditions of rural communities in Bhutan. Rural communities tend to be composed of mainly small and subsistence farmers with limited access to fertile land who live in remote, mountainous terrain. These areas are characterised by low levels of literacy, considerable deprivation, and poverty in terms of access to income and economic opportunities, lower living standards, and a weaker human assets base (Gross National Happiness [GNH] Commission, Royal Government of Bhutan, n.d.). However, efforts can be seen in terms of the measures aimed at documenting TK by the NBC, which includes the involvement of local communities. This documentation has been carried out in 16 gewogs (an administrative unit composed of a block of villages) across eight dzongkhags (districts). This process has included prior and informed consent as part of surveying and documenting of TK related to the use of *Z. cassumunar* in Lokchina gewog in Chukha dzongkhag in southwest Bhutan (UNDP, 2014). With funding from UNDP, a major project was launched in 2014 aimed at helping Bhutan implement the Nagoya Protocol (UNDP, 2014). In addition, the NBC has proposed to carry out fieldwork to provide additional TK documentation, covering all 20 dzongkhags across the country by the end of the ongoing 11th Five Year Plan (2018). As envisaged, activities for TK documentation will in general involve community meetings for awareness and sensitization on access and benefit sharing and TK documentation, identification of TK holders, and consultations with individual TK holders to document TK (UNDP, 2014).

Conclusion and the Way Ahead

From the above discussion, it is clear that the international access and benefit-sharing regime on biological resources and associated TK, as laid down by the CBD and the Nagoya Protocol, operates on the neoliberal rationality of commodification and facilitation of market exchange. However, it has also been continuously shaped by commitments to ensuring justice and equity to the real custodians and owners of these resources—ILCs. Despite certain weaknesses in the regime in terms of strongly framed rights, comparative standing vis-à-vis the TRIPS Agreement and others, it provides a reasonably robust yet flexible framework for developing countries to devise national regimes, in line with their national contexts, priorities, as well as the needs and aspirations of their ILCs. India and Bhutan are the only two countries in South Asia that have enacted legislation and put in place institutional regimes, which have been operational for a decade or more.

As we have already seen, India has a three tier institutional arrangement at the national, sub-national, and local level, which, while vesting considerable power in the national body, is increasingly becoming more participatory through the strengthening of local level BMCs in terms of legal provisions that are the result of community engagement and mobilization. On the other hand, Bhutan has sought to capitalize on the neoliberal promises of bioprospecting as a key strategy to use its biological resources and associated TK to meet socioeconomic goals, as well as to contribute to the lives of TK holders and ILCs. Despite the fact that the policy and legal landscape is still evolving, an institutional mechanism has been set up and has been functional for quite some time. However, in the process, the state agencies have assumed a primary role, entering into access and benefit-sharing negotiations on behalf of ILCs and TK holders, which may be attributed to low levels of awareness, socioeconomic conditions, and

comparative isolation because of the mountainous terrain. At the same time, Bhutan has also created a favourable environment for TK to thrive through its recognition of traditional medicine as an integral part of its public health delivery system and the efforts of the Department of Traditional Medicine Services in this direction.

Considering the overlap between the access and benefit sharing and the intellectual property rights regime, India has done well to take up steps to achieve a better alignment between the two regimes. The incorporation of a strong disclosure requirement for TK used in patent applications, as well as the greater role of the NBA in patent applications dealing with biological resources and associated TK, will go a long way in preventing the misappropriation of TK in the form of patents without prior informed consent and benefit-sharing agreements. Unlike the Indian Patent Act, the Bhutanese legislation has no requirement for disclosure of the use of genetic resources or associated TK, which makes TK vulnerable to misappropriation. While both India and Bhutan have focussed on documentation of TK, it needs to be backed by stringent legal provisions to prevent misappropriation.

As far as implementation is concerned, unfortunately, both India and Bhutan have not fared very well, although the process in both countries has gathered momentum following the Nagoya Protocol and corresponding policy changes. It cannot be denied that there are many impediments, such as low levels of awareness, socioeconomic conditions, etc., to meaningful participation as equal partners in designing and in implementing access and benefit-sharing provisions by ILCs and TK holders in the two countries. While the basic idea of individuals as autonomous entrepreneurs participating in a neoliberal economy is laudable for its ability to empower, the experience across the world has demonstrated that neoliberal strategies tend to frequently disadvantage the poor and the powerless with the opportunities being “more apparent than real” (Castree, 2010, p. 31). As Vermeulen (2008) noted in her case study of the San in southern Africa who had entered into a benefit-sharing agreement for the commercialization of hoodia, such commodification often takes the form of “desperate exchanges as the last resort to improve their lives” (p. 237). In the absence of the power and means to negotiate on equal terms, this process can never become an act of liberation, emancipation, and empowerment for Indigenous Peoples. Hence, the case for building the capacity of TK holders and ILCs to effectively participate in policy making on issues that directly affect their lives, to protect their TK under an alien regime, and to negotiate contracts cannot be overemphasized. Justice and equity demand that TK holders, who have nurtured their environment and knowledge over time, have control and ownership over it, the right to both grant and refuse access to their TK, as well as a right to a high degree of participation and engagement in structures that manage the resource and associated TK. It is only fair that that when people who are relatively disadvantaged and typically excluded are confronted with very complicated issues such as intellectual property rights and access and benefit sharing, they should have access to expert advice and representation (Overwalle, 2005). Policy regimes need to be increasingly sensitive to the local realities and socioeconomic contexts to ensure that access and benefit sharing does not reinforce existing dominance (for instance, caste hierarchies in Indian villages) and that the most marginalized groups find representation in the process.

The constant challenge for the two countries will be in reconciling the imperatives of a neoliberal world order with a just and equitable framework for ILCs and TK holders, which is truly participatory and not top-down. In this context, the case for arriving at tenable legal provisions geared to the unique context of TK and sensitive to the needs of ILCs and TK holders cannot be overemphasized. Draft access and

benefit-sharing national legislation, as well as amendments to laws already in operation, need to clearly lay down the rights of ILCs over their knowledge vis-à-vis the rights and role of the state. They must recognize upfront the primary rights and powers of Indigenous Peoples to both grant and refuse access through organizations and traditional institutions representing their interests, with the state being the facilitator. There is also a need for provisions in the law recognizing bio-cultural protocols, peoples' biodiversity registers (in the Indian context), as well as customary laws—the terms under which communities may be willing to grant access. Such a law may also provide the terms or clauses of the access and benefit-sharing contract as well as the right to a range of monetary and non-monetary benefits arising out of commercialization, depending on the priorities of the ILCs. In addition, the effectiveness of such a law would be suitably enhanced by remedies or penalties against infringement on the rights conferred. As already discussed, there is need to align a country's patent regime with its access and benefit-sharing regime to create an effective deterrent to misappropriation of TK. Finally, efforts at the national level on the part of developing countries need to be backed up by concerted action at the international level in forums like the TRIPS Council, WIPO, and CBD to make the international regime more equitable and beneficial to developing countries and ILCs.

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