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Article

Protection of Traditional Knowledge Use, Access, and Control in Modern Knowledge Economies

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Abstract: Traditional Knowledge (TK) has increasingly become a site of economic contestation in the global digital economy, where advances in biotechnology, data analytics, and cross-border research have intensified the commercial and scientific use of genetic resources. While international legal instruments acknowledge the importance of protecting TK and ensuring equitable benefit-sharing, existing regulatory frameworks remain fragmented, unevenly enforced, and often ill-suited to address the realities of digital dissemination and commercialization. This paper examines the regulation of TK through the lens of economic governance, focusing on how law mediates access, control, and value extraction from genetic resources. Part I situates TK within intellectual property discourse and outlines the conceptual and economic stakes of its protection. Part II analyzes global legal regimes governing TK—particularly under biodiversity and trade law—followed by a detailed examination of India's statutory and institutional framework. Part III identifies structural shortcomings in the current regime and proposes pathways for reform aimed at strengthening legal certainty, economic justice, and regulatory coherence in the global digital economy.

KEYWORDS: Regulating Commercial and Scientific Use of Genetic Resources in the Global Digital Economy.

INTRODUCTION

Traditional Knowledge (TK) has emerged as one of the most contested sites of legal regulation in contemporary intellectual property discourse. Once treated as peripheral to formal systems of innovation, TK now occupies a central position in debates surrounding access to genetic resources, bioeconomic development, and the distribution of value in a globalized and increasingly digital economy. Advances in biotechnology, pharmaceutical research, agricultural science, and data analytics have rendered TK economically legible and commercially exploitable on an unprecedented scale. As a result, legal systems are increasingly called upon to mediate competing claims over control, use, and benefit-sharing arising from knowledge that is collectively generated, culturally embedded, and historically marginalized within dominant intellectual property frameworks.

The regulatory challenge posed by TK is not merely conceptual but structural. Intellectual property law, as it has developed in both domestic and international contexts, is premised on assumptions of individual authorship, novelty, fixation, and limited duration. TK, by contrast, is cumulative, inter-generational, and often inseparable from the ecological contexts in which it is produced and maintained. The resulting mismatch has historically left TK vulnerable to appropriation, particularly when it serves as an informational input into commercially valuable innovation without generating corresponding legal entitlements for its holders.

In response, international legal developments over

the past three decades have increasingly shifted away from orthodox IP solutions and toward regulatory models grounded in biodiversity law, sovereign control. over genetic resources, and principles of equity and benefit-sharing. This shift reflects an implicit recognition that TK raises questions not simply of recognition or moral entitlement, but of economic governance. Legal rules governing access to genetic resources, conditions of use, and mechanisms of benefit-sharing shape the allocation of value within global innovation markets.

This Part lays the conceptual foundation for the analysis that follows. It situates TK within broader debates on intellectual property, examines the economic logic underlying its commercialization, and explains why existing IP frameworks have struggled to regulate its use effectively. In doing so, it frames TK protection as a question of regulatory design in the global digital economy, rather than as a marginal or exceptional problem.

Understanding Traditional Knowledge vis-à-vis Intellectual Property

Traditional Knowledge is often described in cultural or anthropological terms, emphasizing its role in sustaining livelihoods, preserving biodiversity, and maintaining social identity. While these dimensions are central to any normative account of TK, they do not fully capture the reasons for its growing prominence within legal and economic discourse. TK has become legally salient precisely because it functions as an economically valuable resource within contemporary systems of innovation.

In sectors such as pharmaceuticals, nutraceuticals, cosmetics, and agriculture, TK operates as a form of informational capital. It guides research trajectories, reduces uncertainty, and lowers the cost of discovery by identifying biologically active substances, cultivation techniques, or therapeutic applications that have already been empirically tested through long-term use. From an economic perspective, TK thus performs a signaling function, directing scientific inquiry toward commercially promising pathways that might otherwise remain unexplored or prohibitively expensive.

However, the economic value of TK is rarely realized at the point of its creation or use within local communities. Instead, value is typically extracted downstream, through processes of scientific validation, product development, and market commercialization undertaken by actors with access to capital, infrastructure, and legal expertise. The legal framework governing TK therefore plays a critical role in determining whether and how upstream contributors participate in the economic returns generated by their knowledge.

The digital economy has intensified these dynamics. Digitization enables TK to be recorded, catalogued, and transmitted across borders with minimal friction. Databases of medicinal plants, genomic libraries, and ethnobotanical records have become integral to research and development processes, often detached from the communities that generated the underlying knowledge. While digitization enhances efficiency and innovation, it also exacerbates existing asymmetries by facilitating extraction without corresponding mechanisms of accountability or compensation.

The Limits of Conventional Intellectual Property Protection

The difficulty of accommodating TK within conventional intellectual property regimes has been widely acknowledged. Patent law, which plays a central role in regulating commercial innovation, is particularly ill-suited to protecting TK in its existing form. The requirements of novelty and inventive step systematically disadvantage knowledge that is widely shared, incrementally developed, and orally transmitted. Even where TK informs patented inventions, it is frequently treated as background information rather than as a source of entitlement.

This structural bias has significant economic implications. By enabling exclusive rights over innovations derived from TK while denying comparable protection to TK itself, patent law facilitates a transfer of value from traditional knowledge holders to commercial entities. Defensive protection strategies—such as documenting TK to establish prior art—may prevent the grant of invalid patents, but they do little to address questions of benefit-sharing or control over use. In economic terms, such strategies operate as safeguards against exclusion rather than as mechanisms for participation.

Other IP tools, including geographical indications and copyright, offer only partial solutions. Geographical indications may protect certain TK-linked products, but their utility is limited to specific categories of goods and market contexts. Copyright protection, meanwhile, is largely inapplicable to knowledge systems that lack identifiable authorship or fixation. These limitations underscore a broader point: intellectual property law was not designed to regulate collective, long-term knowledge systems that function outside market-oriented incentives.

The persistence of these mismatches has prompted calls for sui generis protection tailored to the specific characteristics of TK. Yet even sui generis models raise difficult questions regarding scope, enforcement, and international recognition. Without effective cross-border mechanisms, domestic TK protection risks being undermined by transnational research practices and global value chains.

The Emergence of Biodiversity-Based Regulatory Frameworks

Recognizing the inadequacy of conventional IP

approaches, international legal efforts have increasingly turned to biodiversity law as a framework for regulating TK. The Convention on Biological Diversity (CBD) marked a significant departure from earlier models by asserting national sovereignty over genetic resources and linking access to obligations of prior informed consent and equitable benefit-sharing. Associated traditional knowledge was brought within this framework as an integral component of biodiversity conservation and sustainable use.

This regulatory shift reflects a reconceptualization of TK protection. Rather than granting exclusive rights, biodiversity-based frameworks seek to govern transactions involving genetic resources and associated knowledge. The emphasis is on regulating access, ensuring consent, and redistributing benefits, rather than on commodifying knowledge through proprietary entitlements. From an economic standpoint, this approach aims to correct market failures arising from information asymmetries, unequal bargaining power, and externalization of social and environmental costs.

The Nagoya Protocol further elaborated this model by establishing more detailed rules on access and benefit-sharing (ABS), including compliance obligations for user countries. However, the effectiveness of these instruments depends heavily on domestic implementation and institutional capacity. Provider countries must establish clear legal frameworks, while user countries must adopt measures to ensure that their nationals comply with foreign ABS requirements. The uneven development of such mechanisms has limited the practical impact of international commitments.

Moreover, biodiversity-based frameworks were largely designed in response to physical access to genetic resources. Contemporary research increasingly relies on digital sequence information and remote data analysis, raising questions about whether existing ABS models can adequately regulate non-physical forms of access. This tension is particularly salient in the context of the global digital economy, where information flows transcend territorial boundaries.

Traditional Knowledge in the Global Digital Economy

The global digital economy has transformed the conditions under which TK is accessed, used, and commercialized. Digital technologies facilitate the aggregation and analysis of vast amounts of biological and ethnographic data, enabling innovation at a scale and speed that existing legal frameworks struggle to regulate. While these developments have generated significant economic value, they have also exposed the limitations of territorial, consent-based regulatory models.

For traditional knowledge holders, digitization presents both opportunities and risks. On the one hand, digital documentation can support defensive protection, cultural preservation, and visibility. On the other hand, it can accelerate misappropriation by making knowledge accessible to actors beyond the reach of domestic legal systems. The economic consequences of this imbalance are reflected in persistent disparities between the value generated by TK-based innovation and the benefits accruing to source communities.

These challenges underscore the need to reassess existing legal regimes through an economic lens. TK protection cannot be reduced to symbolic recognition or isolated legal instruments. It requires coherent regulatory strategies capable of addressing contemporary modes of innovation and value extraction. This paper adopts that perspective, examining how global and national legal frameworks govern the commercial and scientific use of genetic resources and associated TK.

The Fragmented Architecture of Legal Framework

The international regulation of Traditional Knowledge and genetic resources has evolved through a fragmented assemblage of treaties, declarations, and institutional processes rather than a unified legal regime. This fragmentation is not accidental. It reflects persistent disagreement over the legal characterization of TK, the appropriate balance between conservation and commercialization, and the role of intellectual property in mediating access to biological resources. As a result, global regulation operates through overlapping normative layers—biodiversity law, trade law, and intellectual property governance—each advancing distinct economic logics and regulatory priorities.

At the structural level, international law distinguishes between genetic resources as tangible biological material and traditional knowledge as associated, intangible information. While genetic resources are increasingly treated as objects of sovereign control, TK is often addressed indirectly, framed as an adjunct to biodiversity conservation rather than as an independent economic asset. This positioning has material consequences. By subsuming TK within broader environmental regimes, international law limits the scope of enforceable obligations relating to its use, leaving benefit-sharing largely contingent on domestic legal frameworks and contractual arrangements.

From an economic perspective, this regulatory architecture seeks to reconcile competing objectives. On one hand, it aims to facilitate scientific research and technological innovation by maintaining access to biological inputs. On the other, it aspires to correct distributive inequities arising from the historical

extraction of biological resources and knowledge from the Global South. The tension between these objectives runs through all major international instruments governing TK.

The Convention on Biological Diversity: Sovereignty, Access, and Value Allocation

The Convention on Biological Diversity (CBD) represents the foundational shift in the global governance of genetic resources and associated TK. By affirming the sovereign rights of states over biological resources within their territories, the CBD dismantled the earlier notion of genetic resources as part of the common heritage of mankind. This move restructured the economic landscape of biodiversity use, transforming genetic resources into regulated assets whose access could be conditioned on negotiated terms.

Article 15 of the CBD establishes that access to genetic resources shall be subject to prior informed consent and mutually agreed terms. Although the provision does not explicitly mention TK, its economic implications extend to knowledge systems that render genetic resources commercially valuable. Article 8(j) addresses TK more directly, urging states to respect, preserve, and maintain knowledge relevant to biodiversity conservation and to promote equitable benefit-sharing. However, the non-mandatory language of Article 8(j) limits its normative force, leaving states considerable discretion in explaining how, and to what extent, TK is protected.

Economically, the CBD's access-and-benefit-sharing model is designed to internalize the externalities associated with biodiversity exploitation. By linking access to benefit-sharing, the Convention seeks to align incentives for conservation with commercial utilization. Yet, in practice, the translation of sovereign rights into economic gains has been uneven. Provider countries frequently lack the negotiating leverage, technical expertise, or institutional infrastructure required to secure meaningful benefits from access agreements.

Moreover, the CBD's state-centric framework raises questions regarding the position of indigenous and local communities. While states exercise sovereignty over genetic resources, TK is often held collectively by communities whose interests may not align neatly with national development agendas. The absence of clear international standards governing community consent and benefit-sharing has resulted in variable domestic approaches, some of which prioritize state control over community participation.

The Nagoya Protocol: Formalizing Compliance and Transactional Governance

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted to strengthen the operational dimensions of the CBD's ABS framework. Unlike the CBD, the Protocol imposes more specific obligations on both provider and user states, including measures to ensure compliance with foreign ABS requirements.

A central innovation of the Nagoya Protocol lies in its emphasis on user-country obligations. Articles 15 and 16 require parties to take measures to ensure that genetic resources and associated TK utilized within their jurisdictions have been accessed in accordance with prior informed consent and mutually agreed terms. This shift reflects an economic recognition that effective regulation must extend beyond the point of access to encompass downstream use and commercialization The Protocol also explicitly recognizes TK associated with genetic resources, requiring parties to take measures to ensure that access to such knowledge is subject to community consent where applicable. From an economic standpoint, this provision aims to strengthen the bargaining position of TK holders by embedding consent requirements within formal regulatory processes.

Despite these advances, the Nagoya Protocol has faced significant implementation challenges. The diversity of domestic ABS laws, coupled with limited monitoring and enforcement mechanisms, has constrained its effectiveness. Transaction costs associated with negotiating access agreements can deter research, particularly non-commercial scientific inquiry, while weak compliance measures allow opportunistic behavior to persist. The result is a regulatory environment characterized by legal uncertainty and uneven economic outcomes.

Trade Law, Intellectual Property, and the Limits of Integration

Parallel to biodiversity-based regulation, TK intersects with international trade and intellectual property law, most notably under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS does not explicitly address TK or genetic resources, but its patent provisions have been central to debates over biopiracy and misappropriation.

Article 27 of TRIPS requires patents to be available for inventions in all fields of technology, subject to limited exceptions. In the absence of disclosure requirements relating to the origin of genetic resources or TK, patent applicants may obtain exclusive rights over innovations derived from such knowledge without triggering benefit-sharing obligations. This disconnect between patent law and biodiversity law undermines the economic objectives of the CBD and Nagoya Protocol.

Efforts to bridge this gap—through proposals for mandatory disclosure of origin or evidence of prior informed consent in patent applications—have encountered resistance from developed countries

concerned about increased compliance burdens and potential impacts on innovation incentives. The stalemate reflects deeper disagreements over whether patent law should serve distributive functions or remain narrowly focused on incentivizing technological development.

From an economic perspective, the absence of integration between TRIPS and ABS regimes facilitates regulatory arbitrage. Commercial actors can exploit jurisdictional and doctrinal gaps to capture value without engaging with provider-country obligations. This dynamic disproportionately affects TK holders, whose contributions remain legally invisible within patent-centric innovation systems.

WIPO and the Search for Sui Generis Protection

In response to the limitations of existing regimes, the World Intellectual Property Organization (WIPO) has pursued negotiations aimed at developing international legal instruments for the protection of TK, traditional cultural expressions, and genetic resources. These efforts reflect growing recognition that biodiversity-based regulation alone may be insufficient to address the economic realities of TK commercialization.

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has debated a range of options, from defensive protection mechanisms to positive rights frameworks. While consensus remains elusive, draft texts indicate an emerging willingness to acknowledge TK as a subject of legal protection in its own right.

Economically, sui generis approaches seek to recalibrate value allocation by granting TK holders greater control over use and commercialization. However, concerns persist regarding enforceability, compatibility with existing IP systems, and the risk of further fragmenting the international legal landscape. The absence of binding outcomes to date underscores the political and economic complexities inherent in global TK governance.

India's Legal Framework: Statutory Design and Economic Objectives

India represents one of the most developed domestic approaches to regulating genetic resources and associated TK. The Biological Diversity Act, 2002, implements India's obligations under the CBD and establishes a comprehensive ABS framework. The Act asserts state sovereignty over biological resources while creating institutional mechanisms to involve local communities in decision-making.

Under the Act, access to biological resources by foreign entities requires prior approval from the National Biodiversity Authority (NBA), while benefit-sharing arrangements are mandated for commercial utilization. The legislation explicitly recognizes the role of local communities and provides for the establishment of Biodiversity Management Committees (BMCs) at the local level.

Economically, the Indian framework seeks to balance conservation with development. By regulating access and mandating benefit-sharing, the Act aims to ensure that commercialization of biological resources contributes to local and national economic objectives. However, the effectiveness of this model depends on administrative capacity and the ability of institutions to negotiate equitable terms.

Traditional Knowledge Digital Library and Defensive Protection

India has also pursued defensive protection strategies through the creation of the Traditional Knowledge Digital Library (TKDL). The TKDL documents traditional medicinal knowledge and makes it accessible to patent offices to prevent the grant of patents based on misappropriated TK.

While the TKDL has been effective in challenging inappropriate patent claims, its economic impact is limited. Defensive protection prevents exclusion but does not generate positive entitlements or revenue streams for TK holders. Moreover, digitization raises concerns regarding access control and potential misuse, particularly as digital data becomes increasingly central to innovation.

Economic Assessment of India's Approach

India's legal framework reflects a pragmatic response to the economic challenges posed by TK commercialization. By combining regulatory control, benefit-sharing obligations, and defensive documentation, it seeks to mitigate misappropriation while preserving innovation incentives. Yet, gaps remain. Benefit-sharing arrangements are often modest, enforcement is uneven, and community participation varies widely across regions.

These limitations highlight broader structural issues common to TK regulation globally: the difficulty of translating legal recognition into economic empowerment, and the challenge of regulating knowledge flows in a digital, transnational context. The Indian experience thus provides valuable insight into both the possibilities and constraints of domestic ABS regimes.

Structural Shortcomings of the Existing Legal Regime

Despite the proliferation of international instruments and domestic legislation addressing Traditional Knowledge and genetic resources, the current legal regime suffers from deep structural shortcomings. These deficiencies are not merely technical gaps but reflect foundational mismatches between the architecture of existing legal frameworks and the realities of contemporary scientific and commercial practice.[54] At their core, most TK-related regimes

remain anchored in territorial, state-centric, and material conceptions of access that are increasingly misaligned with the digital and transnational character of modern innovation.

One of the most persistent shortcomings lies in the fragmentation of regulatory authority. Biodiversity law, intellectual property law, and trade law operate in parallel rather than in concert, producing overlapping but non-integrated obligations. While the Convention on Biological Diversity and the Nagoya Protocol emphasize access regulation and benefit-sharing, intellectual property regimes—particularly patent systems governed by TRIPS—continue to allocate exclusive rights without meaningful engagement with ABS obligations. This disjunction enables regulatory arbitrage, allowing commercial actors to extract value from TK while remaining insulated from provider-country regimes.

A second structural weakness concerns the limited enforceability of international TK norms. Core provisions relating to TK protection—such as Article 8(j) of the CBD—are framed in aspirational language, lacking direct enforcement mechanisms or sanctions. Even where binding obligations exist, as under the Nagoya Protocol, enforcement depends heavily on domestic implementation and political will. In practice, disparities in institutional capacity between provider and user countries undermine the economic objectives of benefit-sharing regimes.

Further, the state-centric orientation of most ABS frameworks often marginalizes indigenous and local communities. Although international instruments increasingly acknowledge community rights, they rarely specify concrete mechanisms for ensuring meaningful participation or direct benefit flows. As a result, TK holders frequently remain dependent on state intermediaries whose priorities may diverge from community interests. This disconnect weakens the distributive promise of TK regulation and perpetuates historical patterns of exclusion.

The Digital Challenge: Intangible Use and Regulatory Obsolescence

Perhaps the most significant challenge confronting existing TK regimes is their inability to regulate digital modes of utilization. Contemporary scientific research increasingly relies on digital sequence information, bioinformatics databases, and remote data analysis, often without physical access to genetic material. These practices fall uneasily within ABS frameworks premised on physical access and territorial jurisdiction.

The economic implications of this shift are profound. Digital utilization enables rapid, large-scale value extraction with minimal transaction costs, while simultaneously eroding the effectiveness of consent-based regulatory models. Provider countries and TK holders may have no visibility into downstream uses of digitized data, let alone the capacity to negotiate benefit-sharing arrangements. The result is a widening gap between value creation and legal accountability.

International debates surrounding digital sequence information (DSI) underscore this tension. While some states advocate extending ABS obligations to digital uses, others resist on grounds that doing so would hinder research and innovation. The absence of consensus reflects deeper disagreements about whether TK protection should adapt to technological change or remain anchored in traditional regulatory paradigms.

Economic Inefficiencies and Incentive Misalignment

Beyond issues of enforceability and scope, existing TK regimes exhibit significant economic inefficiencies. High transaction costs associated with negotiating access agreements can deter legitimate research, particularly non-commercial or publicly funded scientific inquiry. Conversely, weak monitoring and compliance mechanisms allow opportunistic behavior by well-resourced commercial actors.

This imbalance reflects a broader misalignment of incentives. While ABS regimes seek to internalize the social and environmental costs of resource use, they often fail to provide clear, predictable pathways for lawful access. Uncertainty regarding applicable rules, competent authorities, and benefit-sharing expectations discourages compliance rather than promoting it. From an economic governance perspective, a regulatory system that is costly to navigate but easy to circumvent is inherently unstable.

India's experience illustrates these dynamics. Although the Biological Diversity Act establishes a comprehensive regulatory framework, benefit-sharing outcomes have often been modest relative to the commercial value generated. Administrative bottlenecks, uneven enforcement, and limited community capacity constrain the redistributive potential of the regime. Similar patterns are observable across many provider countries.

Re-Conceptualizing TK Protection: From Defensive to Participatory Models

Addressing these shortcomings requires a conceptual shift in how TK protection is framed. Existing approaches have largely emphasized defensive protection—preventing misappropriation through disclosure requirements, documentation, and access controls. While such measures are necessary, they are insufficient to ensure meaningful economic participation by TK holders.

A more effective approach would move toward participatory regulatory models that integrate TK holders into innovation value chains. This does not necessarily entail the wholesale adoption of

proprietary IP rights, but rather the development of legal mechanisms that recognize TK as a source of economic contribution warranting ongoing participation in benefits.

At the international level, this could involve strengthening community-focused provisions within ABS frameworks, including clearer standards for community consent, benefit distribution, and dispute resolution. At the domestic level, laws could mandate direct benefit flows to community institutions rather than relying solely on state intermediaries. Such measures would better align legal structures with the economic realities of TK-based innovation.

Integrating Intellectual Property and Biodiversity Regimes

A second pathway for reform lies in greater integration between intellectual property law and biodiversity law. The persistent disconnect between patent regimes and ABS obligations undermines both systems. Requiring patent applicants to disclose the origin of genetic resources and associated TK, along with evidence of compliance with ABS requirements, would enhance transparency and accountability.

While disclosure requirements alone are not a panacea, they would reduce opportunities for regulatory arbitrage and reinforce the economic objectives of benefit-sharing regimes. Importantly, such measures need not undermine innovation incentives if designed with proportionality and legal certainty in mind.

Internationally, progress on this front has been slow, but recent developments within WIPO and ongoing discussions at the WTO suggest renewed momentum. Binding international standards linking IP rights to ABS compliance would represent a significant step toward coherent global governance of TK.

Responding to the Digital Economy: Adaptive Regulatory Strategies

To remain effective, TK regulation must adapt to the realities of the digital economy. This requires moving beyond purely territorial conceptions of access and developing mechanisms capable of addressing intangible use. Options under discussion include multilateral benefit-sharing mechanisms for digital sequence information, standardized data-use licenses, and global funds supporting conservation and community development.

Such approaches would not eliminate the need for domestic ABS regimes, but they could complement them by addressing uses that escape national jurisdiction. From an economic perspective, multilateral mechanisms may offer greater efficiency and predictability than fragmented bilateral agreements, particularly in a data-driven innovation landscape.

CONCLUSION

Traditional Knowledge has moved from the margins to the center of global debates on intellectual property, biodiversity, and economic justice. Yet, the legal regimes governing its use remain ill-equipped to address the structural realities of the global digital economy. Fragmentation, weak enforceability, and misaligned incentives continue to limit the effectiveness of existing frameworks.

This paper has argued that TK protection must be understood as a problem of economic governance, not merely cultural recognition or environmental stewardship. By examining global and Indian legal regimes through this lens, it has highlighted both the progress achieved and the limitations that persist. The pathways for reform identified here—greater legal integration, participatory benefit-sharing, and adaptive responses to digital use—offer a basis for rethinking TK regulation in a manner that is both economically sound and normatively just.

If TK is to be protected meaningfully in the twenty-first century, law must evolve beyond defensive postures and toward regulatory strategies that recognize traditional knowledge holders as enduring participants in global innovation systems.

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