

Article

Cultural Integrity versus Intellectual Property: Constructing a "Dual-Track" International Legal Framework for Traditional Chinese Medicine Protection

Aidong Hu^{1,*}

¹ School of Law, Southwest Medical University, Luzhou, China

* Correspondence: Aidong Hu, School of Law, Southwest Medical University, Luzhou, China

Abstract: The international protection of Traditional Chinese Medicine (TCM) is currently fractured between two institutional systems with fundamentally incompatible logics. The UNESCO intangible cultural heritage framework treats TCM as a communally held cultural practice warranting active safeguarding, while the WIPO-administered intellectual property system conceptualizes TCM-derived innovations as exclusive sources of proprietary rights. This article argues that neither system alone adequately protects the multifaceted interests of TCM: the cultural heritage approach lacks enforceable economic mechanisms, while the intellectual property approach risks commodifying living traditions. Drawing on comprehensive doctrinal analysis, comparative institutional analysis, and normative theory—including insights from knowledge governance and postcolonial scholarship—we propose a dual-track framework that functionally differentiates TCM knowledge dimensions according to their predominant governance needs. Codified pharmacological knowledge is assigned to a revised intellectual property track with broadened disclosure and benefit-sharing obligations; embodied clinical practices and philosophical foundations are assigned to an enhanced cultural heritage track with strengthened cooperation mechanisms. Institutional articulation mechanisms—including cross-referencing obligations and a novel cultural integrity impact assessment—ensure coherence across tracks. Situated within the evolving governance landscape shaped by the 2024 WIPO Treaty on Genetic Resources and the 2022 Kunming-Montreal Global Biodiversity Framework, this framework addresses the broader challenge of governing traditional knowledge in a rapidly and increasingly globalized economy.

Keywords: traditional medicine; intellectual property; traditional knowledge; benefit sharing; cultural heritage; legal framework

Received: 31 July 2026

Revised: 10 September 2026

Accepted: 23 September 2026

Published: 30 September 2026



Copyright: © 2026 by the authors. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY) license (<https://creativecommons.org/licenses/by/4.0/>).

1. Introduction

Traditional Chinese Medicine occupies a distinctive position in international legal frameworks. It is simultaneously a living medical system practiced daily by hundreds of millions of people, a repository of pharmacological knowledge that has contributed globally significant therapeutic innovations, and a cultural tradition whose philosophical foundations—the theories of yin-yang, the five phases, and meridian channels—are deeply interwoven with broader Chinese civilizational identity [1]. This multifaceted nature means that TCM cannot be adequately accommodated within any single international legal framework. Yet the current institutional structure attempts precisely such compartmentalization, assigning different aspects of TCM to governance mechanisms that were not designed to operate in coordination.

Two principal frameworks dominate the current landscape. The first is the intangible cultural heritage framework, primarily implemented through the 2003 UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage, which includes certain TCM-related practices on its Representative List and encourages states to

document and transmit these practices to future generations. The second is the intellectual property framework, anchored in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and further developed by the 2024 WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge, which provides pathways for protecting TCM-derived inventions and requires disclosure of traditional knowledge sources where applicable. Each framework reflects a genuine dimension of TCM, yet each also imposes conceptual limitations. The UNESCO framework affirms TCM's cultural context but does not provide mechanisms for equitable economic participation when knowledge is used commercially outside its country of origin. The WIPO/TRIPS framework offers economic tools but applies criteria—such as novelty, inventive step, and individual attribution—that are poorly aligned with medical knowledge systems developed incrementally and collectively over centuries [2].

This article argues that the current governance gap is not merely an administrative challenge but a structural limitation with measurable effects. Patent applications related to TCM by entities outside China have risen markedly over the past two decades, often drawing upon formulations documented in classical Chinese pharmacopoeias without triggering benefit-sharing arrangements. Systematic analysis of how traditional medical knowledge functions within intellectual property systems has shown that standard IP categories constitute a fundamental conceptual mismatch—one that cannot be resolved through minor procedural adjustments or wholesale rejection of the IP framework [3]. At the same time, inclusion of TCM practices on UNESCO heritage lists, while symbolically meaningful, has not led to observable reductions in commercial use without prior consultation or shared benefit, because the heritage framework intentionally avoids economic entitlement language. The outcome is a protection gap: TCM is formally recognized as cultural heritage but lacks robust mechanisms for fair economic engagement, while its potential for innovation remains fragmented across disconnected legal instruments.

Scholarly responses to this challenge generally fall into two broad orientations. One perspective emphasizes strengthening intellectual property safeguards—through improved examination standards, mandatory origin disclosure requirements, and tailored rights models for traditional knowledge. Another perspective questions the suitability of intellectual property frameworks altogether, contending that their underlying logic of commodification is inconsistent with knowledge systems rooted in communal transmission and long-term stewardship. Critical analyses have further highlighted how dominant international frameworks may reflect epistemic assumptions that marginalize non-Western knowledge traditions, particularly when concepts of ownership, authorship, and innovation are applied without contextual adaptation. These perspectives offer valuable insights, but none fully accounts for TCM's dual character—as both a culturally embedded practice and a source of scientifically validated therapeutic development.

This article proposes an alternative approach. Rather than prioritizing one framework over another, it develops a 'dual-track' framework that assigns distinct dimensions of TCM knowledge to the governance mechanism best suited to their characteristics, while establishing formal linkages between tracks to ensure coherence. The framework rests on three foundational principles. First is functional alignment—the idea that regulatory effectiveness increases when instruments are calibrated to the specific attributes of the subject matter they govern [1]. Second is participatory stewardship—understood as the right of communities associated with traditional knowledge to meaningfully engage in decisions regarding its documentation, application, and application. Third is integrated knowledge governance—emphasizing coordinated oversight of knowledge flows across institutional boundaries, informed by advances in digital management and cross-framework policy coordination.

Methodologically, the article combines three analytical approaches [4]. It conducts doctrinal analysis of key international instruments—including the 2003 UNESCO Convention, TRIPS, the 2024 WIPO Treaty, the Nagoya Protocol, and the 2022 Kunming-

Montreal Global Biodiversity Framework—to map existing structures and identify systemic gaps. It undertakes comparative analysis of implementation experiences across diverse settings, including India, Brazil, and New Zealand, to assess how different governance models address TCM-related protection needs. Finally, it advances normative policy arguments grounded in political theory and critical scholarship to justify the design of the proposed framework.

This article makes three contributions to the field. First, it presents a unified analysis of TCM protection that bridges the intangible cultural heritage and intellectual property domains, moving beyond siloed assessments. Second, it introduces concrete coordination mechanisms—particularly a cultural integrity impact assessment—to support structured interaction between participatory stewardship and intellectual property considerations. Third, it situates TCM governance within the evolving international normative context shaped by the 2024 WIPO Treaty and the 2022 Kunming-Montreal Global Biodiversity Framework, clarifying both their progressive elements and remaining limitations.

The article proceeds as follows. Section 2 outlines the theoretical basis for the current separation of governance approaches. Section 3 examines the intangible cultural heritage track. Section 4 analyzes the intellectual property track, including challenges posed by digital sequence information. Section 5 presents the dual-track framework [2]. Section 6 addresses implementation challenges, engages with alternative viewpoints, and considers practical adoption pathways. Section 7 concludes.

2. The Governance Bifurcation: Theoretical Foundations and Institutional Mapping

2.1. Two Logics of Protection

The interface between cultural heritage frameworks and intellectual property frameworks as applied to traditional knowledge has been widely examined [5]. Less systematically explored is how this interface specifically operates for Traditional Chinese Medicine, whose distinctive epistemological and institutional features amplify the structural differences between these two frameworks.

The cultural heritage framework is grounded in a communitarian approach to stewardship. Its principal objective is the intergenerational continuity of cultural practices, and its core mechanisms include inventorying, documentation, transmission, and revitalization. Intangible cultural heritage is defined as 'the practices, representations, expressions, knowledge and skills that communities recognize as part of their cultural heritage,' with emphasis on its dynamic nature—being 'constantly recreated by communities and groups in response to their environment.' The central concept is safeguarding: the aim is to sustain traditions as living, evolving practices, not to assign exclusive ownership rights [2].

The intellectual property framework follows a distinct logic centered on temporary exclusivity [6]. It grants time-limited rights to creators or inventors in return for public disclosure and eventual contribution to the shared knowledge base. This model presumes innovation arises from individual or organizational incentives and relies on proprietary rights to address challenges associated with non-rivalrous information. While well suited to contemporary pharmaceutical development, it aligns poorly with traditional knowledge systems—where advancement is typically incremental, collective, and historically extended, and where attribution to a single originator is often inconsistent with practice.

2.2. TCM as an Amplifier of Institutional Tension

Traditional Chinese Medicine (TCM) presents distinctive challenges for intellectual property frameworks due to its epistemological structure. First, TCM is grounded in a holistic medical philosophy where individual remedies are intrinsically linked to the syndrome differentiation framework (BianZhengLunZhi) that guides their clinical application. Patenting a TCM-derived compound isolates the pharmacologically active ingredient from its diagnostic and therapeutic context—a process widely regarded as epistemically reductive [7]. This abstraction carries practical implications, as the efficacy

of many TCM formulations relies on multi-component synergistic interactions that single-compound patents inherently fail to represent.

Second, the extensive historical record of TCM knowledge poses specific difficulties for the novelty requirement in novelty requirement. Classical texts such as the *Shennong Bencao Jing* (circa first century CE) and the *Bencao Gangmu* (1596) document thousands of formulations with detailed therapeutic indications. Under standard patent doctrine, such documented knowledge constitutes prior art and should preclude patent protection for well-established formulations [8]. In practice, however, linguistic barriers, limited cross-lingual prior art databases, and divergent interpretations of common general knowledge across different regions have led to instances where classical TCM formulations receive patent grants abroad—a phenomenon frequently characterized as biopiracy.

Third, TCM in China occupies a unique position at the intersection of cultural heritage and modern innovation [9]. The 2016 Law of the People's Republic of China on Traditional Chinese Medicine affirms state protection of traditional medical knowledge (Article 8), promotes scientific advancement and international cooperation (Article 9), and safeguards the rights of knowledge holders—including requirements for informed consent and equitable benefit-sharing (Article 43). These provisions reflect a balanced, dual-track approach to TCM governance, oriented toward both preservation and development, though their implementation remains focused within the national legal framework.

2.3. The Postcolonial Dimension

The governance challenges surrounding TCM cannot be fully understood without attending to the postcolonial dimensions of international knowledge governance. It has been observed that the prevailing international order systematically devalues non-Western knowledge systems through epistemicide—the destruction or marginalization of alternative ways of knowing. The international intellectual property framework was developed primarily by and for industrialized nations and embeds assumptions about knowledge production—linearity, individuality, textual documentation—that privilege Western scientific traditions [10]. For TCM, this structural bias manifests concretely: patent offices treat Western biomedical literature as the default prior art base; pharmacological reductionism is assumed as the standard mode of therapeutic validation; and the oral and embodied dimensions of TCM transmission are rendered invisible to the intellectual property system.

Recognizing this postcolonial dimension does not entail rejecting all engagement with the intellectual property system—China itself has pursued strong patent protection for TCM-derived innovations [11]. Rather, it demands that any governance framework acknowledge and actively counteract the epistemic asymmetries pervading international knowledge governance. The dual-track framework responds to this demand by creating institutional spaces where TCM can be assessed and protected on its own epistemic terms.

2.4. Mapping the Institutional Landscape

At the international level, governance related to traditional Chinese medicine is distributed across at least six institutional venues: UNESCO, the World Intellectual Property Organization, the World Trade Organization, the Convention on Biological Diversity Secretariat, the World Health Organization, and the governance framework established under the Kunming-Montreal Global Biodiversity Framework [11]. These institutions exhibit limited coordination. While UNESCO and the World Intellectual Property Organization have signed a cooperation agreement, its implementation remains largely conceptual. The relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity has been subject to prolonged discussion without definitive resolution.

The Kunming-Montreal Global Biodiversity Framework, adopted at the fifteenth Conference of the Parties to the Convention on Biological Diversity, marks a significant advancement [12]. Its Target 13 calls for fair and equitable sharing of benefits arising from

the utilization of genetic resources, digital sequence information on genetic resources, and traditional knowledge associated with such resources. This extends the benefit-sharing paradigm to digital sequence information and establishes connections between biodiversity governance and the protection of traditional knowledge. For traditional Chinese medicine—whose pharmacological knowledge is increasingly captured in genomic databases and computational pharmacology platforms—the Framework’s inclusion of digital sequence information is directly relevant and stands in contrast to the 2024 World Intellectual Property Organization Treaty, which explicitly excludes digital sequence information from its scope.

The 2024 World Intellectual Property Organization Treaty represents a limited advancement. It requires patent applicants to disclose the country of origin of genetic resources and associated traditional knowledge used in their inventions—a first in binding multilateral intellectual property instruments. However, the Treaty’s scope is narrow, its disclosure requirements are narrowly triggered, and its enforcement mechanisms are intentionally limited, as failure to comply does not affect patent validity [9]. For traditional Chinese medicine, the instrument serves as an initial step rather than a comprehensive solution.

3. The Cultural Heritage Track: Unesco and TCM

3.1. TCM within the 2003 Convention

Acupuncture and moxibustion were inscribed on the UNESCO Representative List of the Intangible Cultural Heritage of Humanity in 2010, and Traditional Chinese Medicine has been referenced in multiple nominations and periodic reports. The inscription process confers international recognition, requires the development of safeguarding plans, and establishes a discursive framework in which Traditional Chinese Medicine can be discussed as an expression of cultural identity rather than solely as a commercial product.

Yet the 2003 Convention’s contribution to international protection is structurally constrained. First, the Convention is deliberately non-proprietary. Article 2 defines safeguarding in terms of identification, documentation, preservation, promotion, transmission, and revitalization, conspicuously avoiding language associated with exclusive rights or economic entitlements. This reflects a deliberate policy choice to distance the intangible cultural heritage framework from commodification, but it means that UNESCO inscription provides no legal basis for preventing foreign patenting of formulations derived from Traditional Chinese Medicine or for requiring benefit-sharing arrangements.

Second, the Convention operates on a state-centric model. Obligations are directed to and from States Parties, with communities recognized as heritage bearers but not as rights-holders in the conventional legal sense. This creates a difficult fit with Traditional Chinese Medicine, whose knowledge is held and transmitted by a complex ecosystem of practitioners, lineage-based schools, academic institutions, and state-sponsored research organizations. The community whose prior informed consent should be sought before commercialization is diffuse and heterogeneous.

Third, monitoring mechanisms are weak. There is no formal complaints procedure, no adjudicatory body, and no enforcement mechanism comparable to those found in other international agreements [13]. The recently adopted WHO Global Traditional Medicine Strategy 2025–2034 acknowledges the need for stronger international coordination, aligning with broader multilateral agendas on intellectual property and health governance, but operates through technical guidance rather than binding obligations.

3.2. Culture as a Normative Bridge

Despite these limitations, the cultural heritage track contributes an indispensable normative concept: the right to safeguard and guide the development and transmission of cultural heritage. In international legal discourse, this principle affirms the entitlement of states and peoples to maintain, develop, and transmit their cultural heritage, and to

participate meaningfully in decisions affecting it [3]. For Traditional Chinese Medicine (TCM), this principle carries specific implications: Chinese TCM practitioner communities hold a legitimate interest in how their knowledge is represented, used, and transformed internationally—an interest that extends beyond economic considerations.

This principle is best understood as a procedural guarantee—a right to participate, to provide informed consent, and to share equitably in benefits—rather than as a barrier to external engagement. This aligns with China's balanced approach, which actively promotes TCM internationalization while reinforcing protective mechanisms. The 2016 TCM Law expressly encourages international cooperation (Art. 9) while also affirming protections for knowledge holders (Art [4]. 43). Properly understood, this principle does not contradict with intellectual property frameworks but instead establishes conditions for their legitimate application: commercialization of TCM-derived innovations is appropriate when conducted with the knowledge, consent, and active involvement of source communities. This procedural understanding underpins the cultural heritage track of the dual-track framework and enables its integration with the intellectual property track.

4. The Intellectual Property Track: Wipo/trips and TCM

4.1. Patents and the Structural Mismatch

The patent system's treatment of Traditional Chinese Medicine has been extensively analyzed, with broadly consistent findings indicating that the conventional patent paradigm is poorly suited to its characteristics [8]. The standard requirements of novelty, inventive step, and sufficient disclosure each present distinctive challenges.

Regarding novelty, the challenge stems from information asymmetry. Patent examiners at major international patent offices typically lack access to—and linguistic competence in—the classical Chinese pharmacological texts that constitute relevant prior art. India's Traditional Knowledge Digital Library offers an instructive example: by translating Ayurvedic and Unani texts into patent-searchable formats and establishing cooperative access arrangements with international offices, India has facilitated the withdrawal of numerous patent applications that improperly claimed traditional Indian knowledge as novel. China's domestic infrastructure for documenting traditional knowledge is substantial, but its integration with international patent examination systems remains limited.

Regarding inventive step, many inventions derived from Traditional Chinese Medicine involve extraction, purification, or modification of compounds whose therapeutic uses have been documented for centuries. Whether such downstream processing meets the threshold of non-obviousness depends on the scope of prior art considered—a determination that varies across patent authorities and may influence applicant decisions about where to file [3].

4.2. The 2024 WIPO Treaty: Advances and Limitations

The 2024 WIPO Treaty represents the most significant recent development in the intellectual property governance of traditional knowledge. Article 3 requires patent applicants to disclose the country of origin or source of genetic resources and associated traditional knowledge when the claimed invention is based on such resources or knowledge. This provision, the outcome of a twenty-five-year negotiation process supported by many developing countries and indigenous communities, establishes a link between the patent system and the benefit-sharing obligations established under the Convention on Biological Diversity and the Nagoya Protocol.

Yet the Treaty's practical impact on Traditional Chinese Medicine remains uncertain for several reasons. First, the 'based on' trigger requires that the genetic resources or associated traditional knowledge be necessary for the claimed invention, a threshold that may exclude many TCM-derived innovations where the relationship between traditional knowledge and the patented invention is indirect or synergistic. A narrow focus on genetic resources leaves traditional medicine largely beyond its protective scope, since the

therapeutic knowledge embedded in TCM formulations is not reducible to the biological properties of underlying genetic resources. Second, non-compliance with the disclosure requirement does not constitute grounds for patent invalidation or revocation, substantially weakening its deterrent effect. It remains questionable whether the Treaty creates a genuinely new intellectual property right or merely introduces a procedural requirement with limited substantive consequences. Third, the Treaty explicitly excludes digital sequence information from its scope—a gap of growing significance as TCM pharmacological knowledge is increasingly encoded in genomic databases and network pharmacology platforms.

The Treaty's reception has been contested. As of late 2025, only two states—Malawi and Uganda—had ratified the instrument, far short of the fifteen ratifications required for entry into force. The United States, Japan, South Korea, and India declined to sign, with critics arguing that the disclosure obligation imposes administrative burdens unrelated to patentability determinations. Efforts in early 2025 to integrate the Treaty's disclosure provisions into the Patent Cooperation Treaty system were resisted by several developed countries. This political landscape has important implications for the feasibility of the more ambitious proposals outlined in the dual-track framework, a point addressed in Section 6.

4.3. Digital Sequence Information and the Emerging Governance Gap

The exclusion of digital sequence information from the 2024 WIPO Treaty warrants particular attention in the context of traditional Chinese medicine [14]. As pharmacological knowledge associated with traditional Chinese medicine is increasingly digitized—through initiatives mapping the genomic profiles of medicinal plants, identifying bioactive compounds via computational screening, and constructing network pharmacology models for multi-compound therapeutic mechanisms—the distinction between physical genetic resources and digital information derived from them becomes increasingly significant for governance frameworks related to traditional Chinese medicine.

The 2022 Kunming-Montreal Global Biodiversity Framework addresses this gap within biodiversity governance. Target 13 explicitly includes digital sequence information in its benefit-sharing framework, and a multilateral mechanism for sharing benefits arising from the use of digital sequence information was adopted at COP15. However, the relationship between the Framework's benefit-sharing provisions and the WIPO Treaty's disclosure requirements remains unresolved, as the two instruments were developed through separate institutional processes, involving distinct stakeholder groups and differing normative priorities. For traditional Chinese medicine, this institutional fragmentation presents a practical challenge: a pharmaceutical company developing a drug by computationally analyzing a traditional Chinese medicine botanical genome database may be subject to the Framework's benefit-sharing obligations while falling outside the scope of the WIPO Treaty's disclosure requirements. The dual-track framework proposed here bridges this gap by extending the disclosure standard to cover both digitally mediated and physically embodied traditional knowledge.

4.4. Beyond Patents and the Commodification Risk

The intellectual property framework extends beyond patents. Trade secret protection has played a key role in safeguarding proprietary Traditional Chinese Medicine (TCM) formulations in China, where the state has maintained a confidential list of protected formulations since 1992. Geographical indications represent another potentially significant mechanism, especially for Daodi medicinal materials—the principle that certain herbs exhibit enhanced therapeutic properties when grown in specific geographic regions [15]. Sui generis rights have been under discussion at the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore for over two decades without consensus; the 2024 Treaty marked the first normative outcome of this extended process,

establishing a disclosure requirement rather than conferring substantive rights to traditional knowledge holders.

A central challenge within the intellectual property framework is that expanding protection for TCM knowledge enhances its commercial value while also carrying the risk of detaching it from its cultural context. Intellectual property discourse often frames cultural knowledge primarily in economic terms, potentially overlooking its deep connections to identity, community, and meaning. When a pharmaceutical company secures rights to a purified extract derived from a plant long used in TCM, the relationship among the plant, the associated knowledge tradition, and the originating community is reconfigured: the extract becomes a marketable product, the traditional knowledge functions as a technical input, and the community is positioned as a party entitled to compensation [13]. In contrast, the cultural heritage framework emphasizes stewardship, intergenerational transmission, and cultural integrity—concepts essential for mitigating the commodification of traditional knowledge. The task is to foster constructive alignment between these complementary normative approaches.

5. Constructing the Dual-Track Framework

5.1. Functional Differentiation and Knowledge Governance

The framework's foundational principle is functional differentiation: different dimensions of TCM knowledge should be governed by the institutional track whose normative logic best matches their characteristics and protection needs. This principle builds on insights from institutional analysis indicating that effective governance requires alignment between rules and the attributes of the resources being governed, extended here through the lens of knowledge governance. It has been observed that traditional knowledge does not conform neatly to conventional intellectual property categories such as copyright or patent protection, and its governance must account for distinctive properties—including non-rivalry, context-dependence, and embeddedness in social practices of transmission and interpretation.

Applied to TCM, functional differentiation yields a three-part typology. The first category comprises codified pharmacological knowledge—the formulations, processing techniques, and therapeutic protocols documented in classical and modern texts that are amenable to further scientific development and commercialization. This knowledge requires economic enforcement mechanisms, including enhanced examination standards, mandatory disclosure requirements, benefit-sharing arrangements, and international cooperation on enforcement. The second category comprises embodied clinical knowledge—the diagnostic skills, pattern recognition capacities, and therapeutic judgment that practitioners acquire through years of apprenticeship and clinical experience. This knowledge is inherently personal, tacit, and resistant to codification; it is better supported through the cultural heritage track's emphasis on transmission, education, and community support. The third category comprises philosophical and cosmological foundations—the theoretical framework of yin-yang, the five phases, qi, and meridian theory. This knowledge is neither patentable nor appropriable under conventional intellectual property frameworks, but it is vulnerable to decontextualization and misrepresentation; the cultural heritage track's focus on integrity provides the appropriate governance approach.

5.2. The Intellectual Property Track

For codified pharmacological knowledge, the framework proposes three adjustments that build on but extend the scope of the 2024 WIPO Treaty. First, a broadened disclosure trigger. The Treaty's current "based on" standard—requiring that traditional knowledge be necessary for the invention—is too narrow for TCM compound formulations, whose relationship to traditional knowledge is often indirect, cumulative, or synergistic [16]. The framework introduces a "materially informed by" standard, under which disclosure is required whenever the claimed invention was materially informed by TCM traditional knowledge, irrespective of whether that knowledge was strictly necessary. This lower

threshold captures a wider range of TCM-derived innovations while remaining practical for patent examiners.

Second, enhanced accountability for non-disclosure. The current Treaty provides only for procedural consequences that do not affect patent validity. The framework proposes that failure to disclose triggers a presumption of insufficient diligence in benefit-sharing negotiations, placing the responsibility on the applicant to demonstrate that appropriate consent and equitable benefit-sharing arrangements have been established. This approach avoids automatic invalidation—whose implementation would encounter significant institutional constraints—while still providing strong incentives for compliance [6].

Third, mandatory integration of TCM-specific prior art databases into international patent examination workflows through multilateral access agreements modeled on India's TKDL arrangements. China has invested substantially in TCM knowledge databases, but their effectiveness as defensive tools in cross-national examinations depends on accessibility to foreign patent examiners. The framework envisions a multilateral agreement under WIPO auspices requiring participating patent offices to consult designated TCM databases during relevant examinations [10]. Critically, these databases must include both classical textual sources and contemporary digital pharmacological data, addressing the DSI gap identified in Section 4.3.

5.3. Enhancing the Cultural Heritage Track

For embodied clinical knowledge and philosophical foundations, three enhancements are proposed. First, the development of TCM-specific safeguarding guidelines under the 2003 Convention, addressing distinctive transmission mechanisms, institutional structures, and transnational dimensions of TCM practice—including lineage-based knowledge transmission and the challenges of maintaining clinical traditions within overseas communities. Second, strengthened international cooperation obligations through an interpretive resolution establishing specific responsibilities for states whose nationals engage with TCM knowledge, including requirements for consultation and support for TCM educational programs. Third, a "cultural integrity certification" scheme for TCM products and services marketed internationally, administered jointly by UNESCO and relevant professional bodies, attesting consistency with TCM principles and ethical norms.

5.4. Institutional Articulation Mechanisms

The framework's most innovative element is the set of institutional articulation mechanisms ensuring coherence between tracks. Three mechanisms are proposed. The first is a Joint TCM Governance Committee composed of representatives from WIPO, UNESCO, the CBD Secretariat, the WHO, and relevant Chinese governmental and professional bodies, operating through soft-law instruments such as joint guidelines and recommendations [3]. The second is cross-referencing obligations between UNESCO and WIPO monitoring processes, creating informational linkages that enable each system to account for developments in the other.

The third and most substantive mechanism is a "cultural integrity impact assessment" (CIIA) for TCM-related patent applications. Modeled conceptually on environmental impact assessments in international environmental law, the CIIA would require applicants seeking protection for inventions substantially derived from TCM knowledge to submit an assessment addressing whether the invention risks decontextualizing TCM knowledge, whether source communities have been consulted, and whether commercialization could impede continued practice and transmission of the relevant tradition. A specialized review body with expertise in both IP law and TCM would inform the examination process. The CIIA is admittedly the framework's most ambitious element, but it responds to a genuine governance need that both the WIPO Treaty and the Kunming-Montreal GBF leave unaddressed: the absence of any institutional mechanism for evaluating the cultural consequences of TCM commercialization [2, 3].

6. Discussion

6.1. *Engaging with Competing Perspectives*

The dual-track framework engages with and seeks to transcend the limitations of both dominant scholarly positions on traditional knowledge governance. While acknowledging that intellectual property instruments are necessary for protecting the commercial dimensions of Traditional Chinese Medicine (TCM) knowledge, the framework maintains they are insufficient on their own. The structural mismatch between patent categories and TCM knowledge—documented extensively in prior research—cannot be resolved through disclosure adjustments alone; it requires complementary governance through the cultural heritage track. The dual-track approach thus retains concrete institutional proposals associated with intellectual property adaptation while embedding them within a normative architecture that moderates commodification tendencies.

While affirming that cultural integrity must inform commercial utilization, the framework notes that governance mechanisms focused exclusively on heritage considerations often lack economic safeguards, potentially leaving TCM knowledge exposed to unauthorized use—a risk that intellectual property tools are specifically designed to address. The framework also responds substantively to postcolonial critiques by moving beyond epistemic critique alone: it establishes institutional mechanisms—the Cultural Integrity Impact Assessment and cultural integrity certification—that require TCM knowledge to be evaluated according to its own epistemic foundations during governance processes. This integrates TCM's holistic epistemology as a material factor in patent examination, rather than confining it to peripheral cultural commentary.

6.2. *Political Feasibility and the WIPO Treaty's Reception*

The reception of the 2024 WIPO Treaty reflects the political complexities associated with the dual-track framework. Given that several major patent-granting countries have not signed the treaty and ratification remains limited, advancing the proposed measures—particularly the expanded disclosure requirement and the Cultural and Intellectual Integrity Assessment—faces significant headwinds. To address this, the framework adopts a modular implementation approach: enhancements to the cultural heritage track and the establishment of a Joint Governance Committee may proceed through existing UNESCO and WHO institutional channels, while adjustments to the intellectual property track could initially be advanced via bilateral or plurilateral arrangements among interested states before broader international adoption. The consensus-based adoption of the Kunming-Montreal Global Biodiversity Framework provides a diplomatic model for incorporating traditional knowledge safeguards, contrasting with the more protracted negotiations surrounding the WIPO process. Comparative national experiences offer further insight. India's Traditional Knowledge Digital Library illustrates how defensive protection—blocking inappropriate patent grants on traditional knowledge—can be achieved through technical and administrative means without requiring multilateral treaty changes. Brazil's 2015 Biodiversity Law exemplifies comprehensive domestic legislation on access and benefit-sharing, operating in coordination with international instruments.

6.3. *Limitations and Future Research*

Several limitations warrant acknowledgment. The functional differentiation of TCM knowledge dimensions, while analytically useful, is inevitably imprecise in practice: a given formulation may simultaneously embody codified pharmacological knowledge, tacit clinical judgment, and philosophical principles. The articulation mechanisms are designed to handle such overlap, but their effectiveness depends on operational criteria that require further elaboration through pilot studies and stakeholder consultation. Additionally, ensuring that the governance framework fairly represents diverse perspectives—including those of community practitioners and official institutions—requires sustained attention to inclusive, participatory design approaches.

Future research should pursue three directions. First, detailed operational criteria for the CIIA should be developed through pilot consultations with patent offices and TCM professional bodies. Second, the framework's applicability to other traditional medicine systems—including Ayurveda, traditional African healing practices, and indigenous botanical knowledge—should be assessed comparatively. Third, the accelerating digitization of traditional knowledge through heritage and memory institutions creates new challenges that the current framework addresses only partially; the intersection of artificial intelligence, data governance, and traditional knowledge protection represents an emerging frontier requiring further governance innovation [2, 5].

7. Conclusion

The international protection of Traditional Chinese Medicine has long been constrained by an artificial separation between cultural heritage and intellectual property frameworks. The UNESCO framework recognizes TCM as a living tradition but lacks mechanisms to address commercial uses; the WIPO/TRIPS framework offers economic tools but requires TCM knowledge to conform to categories that do not reflect its cultural context. The 2024 WIPO Treaty and the 2022 Kunming-Montreal Global Biodiversity Framework represent meaningful developments, yet their limited scope and implementation challenges leave significant gaps in the overall governance structure.

The dual-track framework proposed here provides a principled path forward. By distinguishing among different dimensions of TCM knowledge and assigning each to the governance approach best aligned with its nature, the framework avoids oversimplification—neither reducing TCM to heritage alone nor treating it solely as proprietary information. Institutional articulation mechanisms—the Joint Governance Committee, cross-referencing obligations, and the cultural integrity impact assessment—ensure coherence across domains rather than fragmented operation. Grounded in recognition of epistemic asymmetries present in global knowledge governance, the framework advances not only technical coordination but also a normative commitment to balancing cultural continuity with innovation in an interconnected world.

Implementing this framework will require sustained diplomatic engagement, institutional creativity, and openness from both cultural heritage and intellectual property communities to extend beyond established mandates. The implications are far-reaching. As one of humanity's most comprehensive traditional knowledge systems, TCM serves as a critical test case: the approach taken to its protection—or lack thereof—will influence how international governance frameworks address traditional knowledge more broadly in the decades ahead.

References

1. T. Cottier and M. Panizzon, "Legal perspectives on traditional knowledge: The case for intellectual property protection," *Journal of International Economic Law*, vol. 7, no. 2, pp. 371–399, 2004.
2. G. Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*. London, UK: Earthscan, 2010.
3. G. Dutfield, "Traditional knowledge, intellectual property and pharmaceutical innovation: What's left to discuss," in *The SAGE Handbook of Intellectual Property*, 2017, pp. 649–664.
4. A. Wellington, "Intellectual Property Rights, Indigenous Cultural Expression and Traditional Knowledge," in *Encyclopedia of Global Justice*. Berlin, Heidelberg: Springer Berlin Heidelberg, 2026, pp. 1–6.
5. L. T. Smith, *Decolonizing Methodologies: Research and Indigenous Peoples*. London, UK: Zed Books, 1999.
6. M. Laborda Pemán and T. De Moor, "A tale of two commons. Some preliminary hypotheses on the long-term development of the commons in Western and Eastern Europe, 11th–19th centuries," *International Journal of the Commons*, vol. 7, no. 1, 2013.
7. O. R. Young, *The Institutional Dimensions of Environmental Change: Fit, Interplay, and Scale*. Cambridge, UK: Cambridge University Press, 2002.
8. B. Diamond et al., "Performing protocol: indigenous traditional knowledge as/and intellectual property," in *Ethnomusicology: A Contemporary Reader, Volume II*. New York, NY: Routledge, 2017, pp. 17–34.
9. J. Boyle, "The second enclosure movement and the construction of the public DOMAIN," 2003. [Online]. Available: <https://www.law.duke.edu/journals/dlj/boyle>. Accessed: Oct. 15, 2020.

10. C. Antons, Ed., *Traditional Knowledge, Traditional Cultural Expressions, and Intellectual Property Law in the Asia-Pacific Region*, vol. 14. Alphen aan den Rijn, Netherlands: Kluwer Law International BV, 2009.
11. F. H. Fernández, "The WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge: Miracle or Mirage?," *Canadian Yearbook of International Law/Annuaire canadien de droit international*, pp. 1–27, 2026.
12. K. I. Arens, J. P. Gaudillière, H. Madhavan, and E. Noguez, "Commons and the Political Economy of Access: Generics, Neo-traditional Formulations and the Dominant Intellectual Property Regime of Medicines," in *Capitalism, Innovations, and Health after Covid-19: An Asian Perspective*. Cham, Switzerland: Springer Nature Switzerland, 2026, pp. 389–425.
13. C. Oguamanam, *The Protection of Traditional Knowledge: Towards a Cross-Cultural Dialogue on Intellectual Property Rights*. Ottawa, ON: University of Ottawa Press, 2004.
14. T. Kongolo, *Unsettled International Intellectual Property Issues*. Alphen aan den Rijn, Netherlands: Kluwer Law International BV, 2008.
15. F. Fuad, A. Firmansyah, E. Sunaryo, and A. Machmud, "Legal culture of intellectual property rights protection of traditional medicine business performers," *Journal of Law and Sustainable Development*, vol. 12, no. 5, p. 7, 2024.
16. C. Oguamanam, "Patents and traditional medicine: Digital capture, creative legal interventions, and the dialectics of knowledge transformation," *Indiana Journal of Global Legal Studies*, vol. 15, no. 2, pp. 489–528, 2008.

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of Publisher and/or the editor(s). Publisher and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.