

BIOPIRACY AND INDIGENOUS RIGHTS: LEGAL CHALLENGES AND REMEDIES UNDER INTERNATIONAL AND MALAYSIAN LAW

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ABSTRACT

Biopiracy raises significant legal questions at the intersection of intellectual property law, indigenous rights, and biodiversity governance. It refers to the appropriation of genetic resources and associated traditional knowledge without prior informed consent or equitable benefit-sharing. This article addresses the central research question: to what extent do existing international and domestic legal frameworks adequately regulate access to biological resources and protect the rights of Indigenous communities? Using a doctrinal methodology, the study analyses key instruments, including the TRIPS Agreement, the Convention on Biological Diversity (CBD), and the Nagoya Protocol, alongside relevant domestic legislation. It evaluates how these frameworks structure access and benefit-sharing obligations, and identifies gaps in their implementation and enforcement. Particular attention is given to Malaysia's Access to Biological Resources and Benefit Sharing Act 2017 and the National Policy on Biological Diversity 2016–2025 as case studies within the ASEAN context. The article's contribution lies in clarifying the legal inconsistencies between intellectual property regimes and biodiversity governance, and in assessing the extent to which current frameworks recognise and protect Indigenous custodianship of traditional knowledge. The article concludes that meaningful protection of Indigenous rights requires harmonisation between intellectual property regimes and biodiversity conservation laws, greater community participation in benefit-sharing arrangements, and the creation of mechanisms such as a Global Bio-Collecting Society to ensure that innovation does not perpetuate biocolonial exploitation.

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INTRODUCTION

The relationship between law, knowledge, and power is nowhere more evident than in the global debate over biopiracy the appropriation of genetic resources and traditional knowledge without proper authorisation or fair compensation. In the

late twentieth and early twenty-first centuries, multinational corporations and research institutions have increasingly sought patents for products derived from biological materials and traditional ecological knowledge originating in the Global South. This trend has generated

moral outrage and legal controversy, prompting scholars to describe biopiracy as a “new form of colonialism” that transforms community knowledge into corporate property (Shiva, 1997; Nagan, 2009).

From a legal standpoint, biopiracy exposes the structural imbalance within international intellectual property systems. Frameworks such as the TRIPS Agreement under the World Trade Organization (WTO) and the patent regimes administered by the World Intellectual Property Organization (WIPO) were designed primarily to reward innovation in industrialised economies. However, they often disregard communal or intergenerational forms of innovation—precisely the kind of collective knowledge that underpins Indigenous agricultural, medicinal, and ecological practices (Drahos, 2000; Correa, 2021).

The resulting asymmetry is profound. While developed nations benefit from strong patent protections and access to global markets, resource-rich but economically weaker nations often lose control over their biological heritage. This situation is especially critical in biodiversity hotspots such as Malaysia, Indonesia, India, and Brazil, where local communities serve as custodians of extensive genetic and cultural resources. Despite the introduction of international safeguards through the Convention on Biological Diversity (1992) and its Nagoya Protocol (2010), implementation remains inconsistent and frequently undermined by corporate influence, legal ambiguities, and technological challenges, including the rise of digital sequence information (DSI) (Nehring, 2022; Wynberg, 2023).

Biopiracy cases such as the neem tree patent (EPO, 2005), turmeric’s medicinal claims (WIPO, 1997), and RiceTec’s “basmati-type” variety (ScienceBusiness, 2007) reveal how intellectual property law can enable the commodification of traditional knowledge. These cases underscore the need for

stronger benefit-sharing mechanisms and the recognition of Indigenous peoples as legal rights-holders, not merely as sources of ethnobotanical information. The Malaysian experience through the Access to Biological Resources and Benefit Sharing Act 2017 illustrates an emerging legal approach that attempts to balance national sovereignty, community participation, and international obligations.

This paper adopts a doctrinal and comparative legal approach. It critically examines (1) the evolution of the concept of biopiracy; (2) the interaction between international legal instruments (TRIPS, CBD, and Nagoya Protocol); (3) Malaysia’s domestic legal framework and ASEAN’s collective initiatives; and (4) potential reform strategies to reconcile innovation incentives with Indigenous and environmental rights. Through this analysis, it seeks to demonstrate that biopiracy is not simply an ethical or developmental issue—it is fundamentally a question of justice and legality within the global governance of knowledge and biodiversity.

CONCEPTUAL AND HISTORICAL FOUNDATIONS OF BIOPIRACY

2.1 Defining Biopiracy

Biopiracy, broadly defined, refers to the unauthorised extraction and commercialisation of biological resources and the traditional knowledge associated with them. The term was popularised by environmental activist Vandana Shiva (1997), who described it as the “plunder of nature and knowledge” through Western patent systems that legitimise appropriation. Legally, biopiracy arises when individuals or corporations claim intellectual property rights over genetic materials or processes derived from Indigenous knowledge without complying with access and benefit-sharing (ABS) obligations under the CBD or national legislation (Heinrich et al., 2020).

First, legal biopiracy in a strict sense arises from violations of access and benefit-sharing (ABS) or disclosure obligations. Under instruments such as the Convention on Biological Diversity and its supplementary Nagoya Protocol, users of genetic resources are required to obtain prior informed consent and establish mutually agreed terms with provider states or Indigenous communities. Failure to comply with these procedural requirements such as accessing resources without consent or not sharing benefits constitutes a breach of international and domestic ABS frameworks (Morgera et al., 2014).

Second, patent-based misappropriation refers to the granting of intellectual property rights over inventions derived from genetic resources or traditional knowledge without proper disclosure of origin or evidence of lawful access. Within the framework of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), there is no uniform obligation to disclose the source of genetic materials. This gap has enabled patents to be granted over innovations based on Indigenous knowledge, raising concerns about unjust enrichment and the erosion of community rights (Dutfield, 2011; Mgbeoji, 2006).

Third, broader justice-based critiques conceptualise biopiracy as part of a wider political economy of commodification. From this perspective, the issue is not limited to legal non-compliance but extends to structural inequalities embedded in global intellectual property regimes, which enable the transformation of collectively held knowledge into private property. These critiques emphasise distributive injustice, epistemic marginalisation, and the asymmetrical power relations between developed and developing countries (Shiva, 1997; Robinson, 2010).

Distinguishing between these dimensions clarifies that biopiracy is not a singular legal violation but a multi-layered

concept encompassing breaches of ABS obligations, deficiencies in patent governance, and broader normative concerns about equity and the commodification of biodiversity.

From a doctrinal perspective, biopiracy sits at the intersection of two competing legal philosophies. On one hand, intellectual property law prioritises novelty, inventive step, and industrial applicability criteria developed within a Eurocentric model of individual innovation. On the other hand, Indigenous epistemologies view knowledge as communal, cumulative, and sacred, transmitted orally across generations (Posey & Dutfield, 1996). This epistemic dissonance explains why conventional patent systems often fail to recognise the legitimacy of traditional knowledge as prior art or as a form of intellectual property deserving protection in its own right (Chouchena-Rojas et al., 2022).

2.2 Historical Roots: From Colonial Extraction to Biocolonialism

The phenomenon of biopiracy has deep colonial antecedents. During the nineteenth and early twentieth centuries, European colonial powers systematically extracted plant and seed materials from Asia, Africa, and Latin America to establish agricultural monopolies. The transfer of rubber seeds from Brazil to British Malaya in the 1870s, for instance, exemplified early forms of biological appropriation that reconfigured global trade and labour systems (Brockway, 1979).

Modern biopiracy reproduces this extractive logic in a legalised form. Whereas colonial administrators relied on political domination, contemporary corporations utilise the language of intellectual property and scientific discovery to achieve similar ends. This continuity has led scholars to describe biopiracy as biocolonialism a system that reasserts control over the genetic commons through patents, research partnerships, and

contractual arrangements that privilege corporate interests (Rimmer, 2015; Wiser, 2021).

Importantly, this transformation has been facilitated by technological and legal developments. Advances in biotechnology and genetic sequencing enable researchers to isolate, replicate, and patent specific genetic materials. At the same time, international IP frameworks—especially TRIPS have harmonised patent standards globally, extending Western-style exclusivities into jurisdictions where Indigenous knowledge and communal ownership were previously dominant (Correa, 2021).

2.3 *The Evolution of Legal Responses*

The late 20th and early 21st centuries witnessed an increasing recognition of the need to protect traditional knowledge within international law. The CBD (1992) established the principle of national sovereignty over biological resources, marking a paradigm shift from the earlier “common heritage of mankind” approach. Article 8(j) of the CBD explicitly calls for the respect, preservation, and maintenance of knowledge, innovations, and practices of indigenous communities, while promoting equitable benefit sharing. The subsequent Nagoya Protocol (2010) operationalized these principles by requiring user countries to ensure compliance with access and benefit-sharing (ABS) obligations.

Parallel to these developments, the World Intellectual Property Organization (WIPO) initiated its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC-GRTKF) to explore mechanisms for legal protection (WIPO, 2023). Despite these advances, challenges remain in harmonizing IP frameworks with customary norms, particularly in states with plural legal systems like Malaysia, where statutory law coexists with native customary law.

2.4 *Malaysian lack of a comprehensive sui generis system for protecting traditional knowledge and Biopiracy*

Rohaida Nordin, Kamal Halili Hassan, and Zinatul A. Zainol (2012) critically examine the role of traditional knowledge documentation systems, questioning whether such mechanisms function as tools of protection or inadvertently facilitate misappropriation. Their analysis highlights a central tension: while documentation may prevent erroneous patent grants by establishing prior art, it may also expose sensitive knowledge to wider access without adequate safeguards.

Similarly, Safeguarding Traditional Knowledge in Malaysia by Zaid Ibrahim & Co provides a practice-oriented perspective on the limitations of Malaysia’s legal framework, particularly the lack of a comprehensive sui generis system for protecting traditional knowledge. The report emphasises the need for clearer institutional coordination and stronger recognition of Indigenous custodianship within both intellectual property and biodiversity regimes.

In particular, it supports the argument that Malaysia’s current framework—while progressive in legislative terms remains incomplete in addressing the dual challenges of preventing misappropriation and empowering Indigenous communities. By building on these foundational works, this article extends the discussion beyond documentation and policy critique toward a more integrated assessment of legal coherence between intellectual property law and access and benefit-sharing frameworks.

INTERNATIONAL LEGAL FRAMEWORK

The international legal landscape governing biopiracy and the protection of indigenous traditional knowledge is shaped primarily by three key instruments: the Agreement on

Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Convention on Biological Diversity (CBD), and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits. Each instrument addresses different but interrelated aspects of biodiversity governance, intellectual property, and indigenous rights. However, the tension between trade-driven intellectual property standards and environmental-justice-oriented biodiversity principles remains a persistent obstacle to coherent legal protection.

3.1 The TRIPS Agreement: Intellectual Property and Genetic Resources

The TRIPS Agreement, adopted in 1994 under the World Trade Organization (WTO), set minimum global standards for intellectual property rights, including patents, copyrights, and trademarks. Articles 27(1) and 27(3)(b) of TRIPS are particularly relevant to biopiracy and traditional knowledge. While Article 27(1) requires patents to be available for inventions in “all fields of technology,” Article 27(3)(b) permits but does not require member states to exclude plants, animals, and essentially biological processes from patentability. However, it obliges states to provide protection for plant varieties either through patents or an “effective sui generis system” (TRIPS, 1994).

This flexibility was meant to accommodate differing national circumstances, yet it created significant disparities between developed and developing nations. Developed countries, dominated by multinational biotechnology corporations, adopted broad patent protections covering genetic materials and derivatives. In contrast, developing countries struggled to balance these requirements with their biodiversity-rich but institutionally weaker systems (Okediji, 2018). The lack of mandatory disclosure of origin and evidence of prior informed

consent (PIC) in TRIPS further enables corporations to patent biological materials derived from indigenous knowledge without recognizing their source communities (Correa, 2021).

Scholars have argued that TRIPS effectively legitimizes biopiracy by embedding Western notions of innovation into international law (Drahos, 2016). The agreement’s silence on benefit-sharing and community rights undermines the principles of equity and prior consent enshrined in the CBD. Efforts to amend TRIPS to require mandatory disclosure of genetic resource origins have been ongoing at the WTO, but progress remains limited due to resistance from industrialized countries (WTO, 2023).

3.2 The Convention on Biological Diversity (CBD): Sovereignty and Equity

The Convention on Biological Diversity (CBD), adopted at the 1992 Earth Summit in Rio de Janeiro, represents a landmark shift in international environmental law. Unlike previous frameworks that treated genetic resources as the “common heritage of mankind,” the CBD recognizes the sovereign rights of states over their biological resources (CBD, 1992). This principle forms the legal foundation for regulating access to genetic resources and ensuring that the benefits derived from their utilization are shared fairly and equitably.

Article 8(j) of the CBD is particularly significant in the context of biopiracy. It calls upon parties to “respect, preserve, and maintain knowledge, innovations, and practices of indigenous and local communities” and to promote their wider application with the “approval and involvement of the holders of such knowledge.” Article 15 further obliges states to establish mechanisms ensuring that access to genetic resources occurs only with the prior informed consent (PIC) of the providing country and on mutually agreed terms (MAT).

The CBD's emphasis on sovereign control and equitable benefit-sharing represents a direct counterbalance to the TRIPS framework. However, its effectiveness is constrained by the fact that it operates primarily through national implementation. States must translate the CBD's broad commitments into domestic legislation, which varies widely in scope and enforcement capacity. For instance, while Malaysia has adopted the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795), other ASEAN countries such as Indonesia and the Philippines have taken different regulatory approaches (Latip, 2022; Tambunan, 2023). This fragmented landscape weakens the CBD's capacity to prevent cross-border biopiracy.

Moreover, the CBD lacks a clear mechanism for monitoring compliance or resolving disputes related to unauthorized use of genetic resources. As a result, even when indigenous communities can prove that their traditional knowledge was appropriated, enforcement remains elusive due to jurisdictional and evidentiary challenges (Kamau & Winter, 2013).

3.3 The Nagoya Protocol: Operationalizing Access and Benefit-Sharing (ABS)

To address the CBD's implementation gaps, the Nagoya Protocol was adopted in 2010 and entered into force in 2014. It serves as a legally binding instrument that operationalizes the CBD's provisions on Access and Benefit-Sharing (ABS). The protocol aims to ensure that users of genetic resources—whether states, corporations, or researchers—obtain resources through legally established channels and that benefits arising from their use are shared fairly and equitably with provider countries and indigenous communities (Nagoya Protocol, 2010).

Key principles under the Nagoya Protocol include:

- Prior Informed Consent (PIC): Users must obtain

authorization from the competent authority of the provider country before accessing genetic resources.

- Mutually Agreed Terms (MAT): Access and use must be governed by a contract specifying benefit-sharing conditions.
- Compliance Measures: Parties must ensure that users within their jurisdictions comply with PIC and MAT requirements, including the use of checkpoints to verify legality.
- Recognition of Traditional Knowledge: Article 7 explicitly addresses traditional knowledge associated with genetic resources, requiring that access to such knowledge occur with the approval and involvement of indigenous and local communities.

The Nagoya Protocol has enhanced legal clarity and introduced procedural safeguards against biopiracy. Nevertheless, implementation challenges persist. Many developing countries, including Malaysia, face difficulties in establishing functional ABS systems due to limited institutional capacity, overlapping jurisdiction between federal and state authorities, and lack of awareness among local communities (Latip, 2022; Gurdial Singh Nijar, 2021).

Critics argue that while the Nagoya Protocol introduces procedural justice mechanisms, it does not sufficiently alter the structural inequalities between knowledge holders and commercial actors (Morgera, 2020). The reliance on contractual models assumes parity of bargaining power, which seldom exists between indigenous communities and multinational corporations. Furthermore, the protocol's interaction with TRIPS remains unresolved, leading to a fragmented global governance regime where biodiversity protection and intellectual property enforcement often conflict rather than complement each other.

3.4 The World Intellectual Property Organization (WIPO) and Traditional Knowledge

The World Intellectual Property Organization (WIPO) has played a growing role in mediating between conventional IP regimes and the protection of traditional knowledge. Through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC-GRTKF), WIPO has developed model frameworks for documenting, preserving, and legally protecting traditional knowledge and genetic resources (WIPO, 2023). The committee's negotiations focus on three core objectives: preventing misappropriation, promoting equitable benefit-sharing, and safeguarding cultural integrity.

While WIPO's work remains advisory and has yet to produce a binding international treaty, it has stimulated significant policy innovation at the national level. Countries like India, Peru, and Malaysia have drawn upon WIPO guidelines to establish traditional knowledge databases and prior art registries, which help prevent the granting of illegitimate patents. However, the documentation of traditional knowledge raises ethical and practical questions—such as risks of overexposure, cultural misrepresentation, and loss of community control over sensitive knowledge (Abd Rahman, 2021). Therefore, while WIPO's initiatives enhance legal recognition, they must be coupled with mechanisms that respect indigenous autonomy and cultural confidentiality.

3.5 Interplay Between TRIPS, CBD, and the Nagoya Protocol

The relationship between TRIPS, the CBD, and the Nagoya Protocol illustrates the fragmented nature of global governance on biopiracy. TRIPS promotes uniform patent standards and trade liberalization, whereas

the CBD and Nagoya Protocol emphasize environmental sustainability, equity, and sovereignty. Attempts to reconcile these regimes through “mutual supportiveness” clauses have not eliminated conflicts in interpretation and enforcement (Morgera, 2020). The absence of a binding link between the WTO and CBD frameworks means that corporations can still obtain patents in one jurisdiction based on resources or knowledge acquired unlawfully elsewhere.

Efforts to amend TRIPS to include mandatory disclosure of origin requirements for genetic resources have gained traction since 2008, with proposals tabled by Brazil, India, and other developing countries (WTO, 2023). Such amendments would compel patent applicants to disclose the source of genetic materials and provide evidence of prior informed consent, thereby strengthening accountability. However, progress has been slow, and many developed countries oppose the proposal, citing administrative burdens and concerns over patent system efficiency.

The lack of coherence between these international instruments underscores the need for national-level innovation and regional cooperation. For countries like Malaysia—situated within the biodiverse yet institutionally diverse ASEAN region—harmonizing domestic laws with both TRIPS obligations and CBD commitments remains a pressing challenge.

3.6 Key Limitations in biopiracy

A key limitation in existing scholarship on biopiracy is the tendency to employ terms such as “biocolonialism” and “knowledge colonialism” without sufficient analytical precision. For the purposes of this study, biocolonialism is operationalised as a legally identifiable pattern of resource appropriation characterised by three elements: (i) access to genetic resources or traditional knowledge without compliance with access and benefit-sharing (ABS)

obligations; (ii) the transformation of collectively held knowledge into exclusive private rights through intellectual property regimes; and (iii) the absence of equitable benefit-sharing with source communities. This formulation aligns with scholarly efforts to move beyond rhetorical critique toward legally grounded analysis (Wiser, 2021; Mgbeoji, 2006).

“Knowledge colonialism,” by contrast, is used more narrowly to describe the second element namely, the epistemic and legal privileging of Western models of innovation embedded within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). As discussed in Section 3, TRIPS recognises novelty and inventiveness in individualised terms while failing to accommodate cumulative and communal knowledge systems, thereby facilitating the legal enclosure of traditional knowledge (Drahos, 2016; Correa, 2021).

At the same time, it is necessary to engage with counterarguments that defend the existing intellectual property framework. Proponents of TRIPS argue that strong patent protection is essential for incentivising innovation, particularly in high-cost sectors such as biotechnology and pharmaceuticals (Okediji, 2018). From this perspective, expanding disclosure or ABS-linked requirements could introduce uncertainty into the patent system and potentially deter investment.

However, doctrinal analysis suggests that this position rests on a false dichotomy between innovation and equity. As Correa (2021) argues, mechanisms such as mandatory disclosure of origin, prior informed consent (PIC), and mutually agreed terms (MAT) can be integrated into patent systems without undermining their incentive function. Similarly, Dutfield (2011) notes that failure to incorporate such safeguards risks legitimising unjust enrichment by allowing downstream innovators to benefit from upstream knowledge without compensation. The issue, therefore, is not the existence of

intellectual property rights per se, but their structural disconnection from biodiversity governance frameworks.

This conceptual clarification directly informs the reform proposals advanced in Section 6. The identified tension between TRIPS and the Convention on Biological Diversity (CBD) justifies the call for greater legal interoperability, particularly through disclosure of origin requirements. Likewise, the procedural limitations of the Nagoya Protocol especially its reliance on contractual ABS models despite unequal bargaining power support proposals for stronger institutional oversight and community-based enforcement mechanisms (Morgera, 2020).

At the domestic level, the doctrinal gaps identified in Malaysia’s Access to Biological Resources and Benefit Sharing Act 2017 particularly its limited integration of customary law and fragmented federal–state implementation provide the basis for recommending harmonisation measures and enhanced recognition of Indigenous governance systems. In this way, the article’s reform proposals are not merely normative but are anchored in the structural deficiencies identified across international and domestic legal regimes.

MALAYSIAN AND ASEAN LEGAL CONTEXT

Malaysia, as one of the world’s megadiverse nations, faces a complex legal task in regulating access[DF5.1] to biological resources and protecting Indigenous traditional knowledge within a plural legal system. This section advances a closer statutory analysis of the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795), with particular attention to its jurisdictional scope and its interaction with state-level regimes in Sabah and Sarawak.

Act 795 establishes a federal framework governing access to biological resources and associated traditional knowledge in Peninsular Malaysia and the

Federal Territories. Section 3 defines the scope of “biological resources” and “traditional knowledge,” adopting a broad formulation consistent with the Convention on Biological Diversity. Crucially, Section 12 introduces the requirement for prior informed consent (PIC) from resource providers, while Section 21 mandates the negotiation of mutually agreed terms (MAT), including benefit-sharing arrangements. These provisions operationalise Malaysia’s obligations under the Nagoya Protocol by embedding procedural safeguards into domestic law.

However, a key limitation emerges from the Act’s territorial application. Under Section 1(2), Act 795 does not automatically extend to Sabah and Sarawak, reflecting the constitutional division of legislative powers over land, forests, and natural resources under the Federal Constitution of Malaysia. In practice, this means that access to biological resources in East Malaysia is governed primarily by state legislation rather than federal law.

In Sabah, bioprospecting activities are regulated under the Sabah Biodiversity Enactment 2000, which establishes the Sabah Biodiversity Council and requires permits for access to biological resources. Similarly, Sarawak regulates access through the Sarawak Biodiversity Centre Ordinance 1997, which vests authority in the Sarawak Biodiversity Centre to control research and commercial use of biological materials. While these state laws reflect principles analogous to PIC and benefit-sharing, they differ in procedural requirements, institutional structures, and enforcement mechanisms.

The interaction between Act 795 and these state regimes is therefore non-harmonised and jurisdictionally fragmented. In practice, researchers and corporations must navigate multiple approval processes depending on the geographic location of the resources. For example, a project involving cross-border sampling between Peninsular Malaysia and

Sarawak would require separate compliance with Act 795 and Sarawak’s ordinance, potentially leading to regulatory duplication and legal uncertainty. Moreover, Act 795 does not provide a clear coordinating mechanism for inter-jurisdictional cases, nor does it establish mutual recognition of permits issued by state authorities.

From a doctrinal perspective, this fragmentation raises questions about the consistency of ABS implementation across Malaysia. While Act 795 aligns closely with international standards, the absence of uniform application across all territories may undermine legal certainty and weaken the protection of Indigenous rights, particularly where customary law intersects with statutory regimes. Native customary rights (NCR), especially in Sabah and Sarawak, are recognised through a combination of statutory provisions and judicial interpretation, yet Act 795 does not explicitly integrate NCR-based consent processes into its federal framework.

Comparatively, ASEAN states such as the Philippines have adopted more centralised ABS regimes (e.g., Executive Order No. 247), though challenges of enforcement persist. Malaysia’s approach, by contrast, reflects a constitutionally grounded decentralisation that prioritises state autonomy but complicates regulatory coherence.

In sum, a section-specific reading of Act 795 reveals that while Malaysia has established a procedurally robust ABS framework at the federal level, its limited territorial reach and lack of integration with Sabah and Sarawak laws create practical and doctrinal gaps. Addressing these issues would require clearer mechanisms for federal–state coordination, greater harmonisation of procedural standards, and explicit recognition of Indigenous customary governance within the statutory scheme.

4.1 The Access to Biological Resources and Benefit Sharing Act 2017 (Act 795)

The Access to Biological Resources and Benefit Sharing Act 2017 (Act 795) represents Malaysia's first comprehensive attempt to regulate access to genetic resources and traditional knowledge in accordance with the Convention on Biological Diversity (CBD) and the Nagoya Protocol. It establishes a legal framework to ensure that biological resources and associated traditional knowledge are accessed only with authorization and that benefits arising from their utilization are shared equitably.

Under Section 12 of Act 795, any person intending to access biological resources or associated traditional knowledge must obtain a permit from the competent authority, currently the Ministry of Natural Resources, Environment, and Climate Change (NRECC). Access applications require the consent of both the resource provider and the relevant indigenous or local community, reflecting the principle of Prior Informed Consent (PIC). The Act further mandates that benefit-sharing be governed by Mutually Agreed Terms (MAT), in line with international standards.

Section 24 of Act 795 provides that benefits—whether monetary (such as royalties) or non-monetary (such as technology transfer and research collaboration)—must be distributed fairly among stakeholders. Section 27 criminalizes unauthorized access and misappropriation of biological resources, providing for fines and imprisonment. However, critics argue that enforcement mechanisms remain underdeveloped, particularly in terms of community capacity-building and monitoring compliance at the research and commercialization stages (Latip, 2022).

Furthermore, the Act applies primarily to federal territories and Peninsular Malaysia, while Sabah and Sarawak maintain autonomy under their respective State Biodiversity Enactments. This division of authority creates inconsistencies in the application of ABS

principles across Malaysia's territories. For instance, Sabah enacted its Biodiversity Enactment 2000, which established the Sabah Biodiversity Centre (SaBC), while Sarawak enacted the Sarawak Biodiversity Centre Ordinance 1997, both of which predate Act 795 and operate independently. Coordination between federal and state authorities remains limited, potentially creating loopholes that bioprospectors could exploit.

4.2 Indigenous Rights and Customary Law in Malaysia

Malaysia's indigenous peoples comprising the Orang Asli in Peninsular Malaysia and native communities in Sabah and Sarawak possess deep traditional knowledge of medicinal plants, forest ecology, and biodiversity. However, their rights to land and natural resources are only partially recognized under Malaysian law. The Aboriginal Peoples Act 1954 provides limited recognition and protection, primarily through the establishment of Aboriginal reserves, but it does not confer ownership rights over land or resources. Consequently, indigenous communities often lack legal standing to assert claims over biopiracy or unauthorized bioprospecting activities (Nicholas, 2020).

In contrast, native customary law in Sabah and Sarawak carries stronger legal weight under Article 161A of the Federal Constitution, which recognizes native customary rights (NCRs). Judicial precedents, such as *Sagong bin Tasi v. Kerajaan Negeri Selangor* [2005] 6 MLJ 289, have affirmed that indigenous customary land rights are protected under Article 13 of the Federal Constitution, which safeguards against the deprivation of property without compensation. Although this case addressed land rather than biological resources, it establishes a constitutional foundation for recognizing indigenous control over territories where traditional knowledge is embedded.

Recent policy developments, such as the National Policy on Biological Diversity 2016–2025, reinforce Malaysia’s commitment to empowering indigenous communities as biodiversity stewards. Strategy 6 of the policy explicitly calls for enhancing “community participation in biodiversity management” and promoting the use of traditional knowledge systems. Nonetheless, practical implementation has been slow, and indigenous participation in decision-making remains largely consultative rather than determinative (Mohd Yusoff & Hashim, 2021).

4.3 Case Law and Emerging Jurisprudence

Malaysia lacks direct judicial precedents dealing specifically with biopiracy or access and benefit-sharing (ABS) disputes. While analogies are sometimes drawn from cases concerning Indigenous land rights and environmental protection, such reliance must be carefully qualified. Judicial recognition of native customary rights (NCR) for example in *Adong bin Kuwau v Kerajaan Negeri Johor* and *Nor Anak Nyawai v Borneo Pulp Plantation Sdn Bhd* primarily affirms usufructuary interests in land and resources. These decisions establish rights of occupation, use, and livelihood, but they do not, without more, confer proprietary ownership or regulatory control over genetic resources or associated traditional knowledge.

This distinction is significant in the context of ABS frameworks under the Convention on Biological Diversity and the Nagoya Protocol, which are premised on state sovereignty over biological resources and structured consent procedures rather than private ownership claims. Accordingly, Malaysian case law on NCR cannot be read as directly establishing legal entitlement to control access to genetic materials or to claim benefits arising from their utilisation. At most, such cases provide contextual support for recognising Indigenous communities as legitimate stakeholders whose customary

relationships with land and biodiversity may justify participatory rights in consent and benefit-sharing processes.

From a doctrinal perspective, the absence of biopiracy-specific litigation means that the legal status of traditional knowledge and genetic resources remains underdeveloped in Malaysian jurisprudence. Courts have not yet addressed whether, and to what extent, existing doctrines—such as fiduciary duties, unjust enrichment, or statutory interpretation under the Access to Biological Resources and Benefit Sharing Act 2017 can be extended to disputes involving unauthorised use of biological resources. Consequently, while Indigenous land rights cases are analytically relevant, they should not be overstated as establishing a legal foundation for ownership or control over genetic resources; rather, they highlight normative considerations that may inform future judicial or legislative developments.

In *Kerajaan Negeri Johor v. Adong bin Kuwau* [1998] 2 MLJ 158, the High Court recognized the usufructuary rights of the Orang Asli to hunt, fish, and gather forest produce within their traditional territories. The court held that these rights were protected under Article 13 of the Federal Constitution. This decision, later upheld by the Court of Appeal, established that indigenous resource use rights constitute property deserving constitutional protection. The judgment, though not explicitly addressing bioprospecting, provides a legal foundation for indigenous claims to control and benefit from biological resources within their territories.

Another relevant case, *Superintendent of Lands & Surveys Miri Division v. Madeli bin Salleh* [2007] 6 CLJ 509, reaffirmed that native customary rights predate statutory law and must be recognized as such. The Federal Court emphasized that indigenous occupation and resource use constitute lawful property interests even without formal title. This principle could be extended to argue that

traditional knowledge associated with biological resources should similarly be recognized as a form of intangible property.

Comparatively, Malaysia's courts have also drawn upon environmental jurisprudence, such as *Kajing Tubek v. Ekran Berhad* [1996] 2 MLJ 388, where the court recognized the need for environmental impact assessments that respect indigenous rights. These cases collectively demonstrate an emerging judicial sensitivity to indigenous issues, although an explicit recognition of traditional knowledge as property remains absent.

4.4 ASEAN Regional Developments

Within the ASEAN framework, there is growing recognition of the need for collective action to prevent biopiracy. The ASEAN Centre for Biodiversity (ACB), established in 2005, serves as a regional coordinating body promoting biodiversity conservation and the implementation of the CBD and Nagoya Protocol. The ASEAN Strategic Plan on the Convention on Biological Diversity (2016–2025) identifies the development of regional guidelines on access and benefit-sharing as a strategic priority.

Indonesia provides a valuable comparative example. The country's Law

No. 11 of 2013 ratified the Nagoya Protocol, and its Government Regulation No. 6 of 2016 on Access to Genetic Resources establishes clear mechanisms for obtaining prior informed consent from local communities. Indonesia has also created traditional knowledge databases (TKDL) modeled after India's system to prevent patent misappropriation (Tambunan, 2023). In contrast, the Philippines' Indigenous Peoples' Rights Act 1997 (IPRA) goes further by explicitly recognizing indigenous ownership of ancestral domains and traditional knowledge, requiring free, prior, and informed consent (FPIC) for any access or commercial use.

These regional developments highlight Malaysia's relative progressiveness in legislative enactment but underline persistent gaps in enforcement and indigenous empowerment. The absence of a harmonized ASEAN framework allows cross-border bioprospecting to occur with minimal oversight. Hence, regional legal cooperation potentially through an ASEAN Protocol on Genetic Resource Protection could enhance both national and collective resilience against biopiracy.

Comparative Analysis of ABS Frameworks in Selected ASEAN Jurisdictions.

Dimension	Malaysia	Indonesia	Philippines
Consent Regime	Prior informed consent (PIC) required under Access to Biological Resources and Benefit Sharing Act 2017 (ss. 12–15), but implementation varies across federal–state jurisdictions	PIC mandated under Government Regulation No. 6 of 2016; includes administrative procedures for state and community approval	Free, Prior and Informed Consent (FPIC) explicitly required under Indigenous Peoples' Rights Act 1997, with strong procedural safeguards
Recognition of Community Rights	Implicit and procedural recognition; no explicit proprietary rights over genetic resources or traditional knowledge	Limited explicit recognition; communities consulted but state retains primary control	Strong recognition of Indigenous ownership over ancestral domains and traditional knowledge

Enforcement Mechanisms	Statutory offences and permit system under Act 795, but limited case law and fragmented enforcement across regions	Centralised administrative enforcement with licensing requirements; implementation capacity varies	Institutional enforcement through National Commission on Indigenous Peoples (NCIP), though practical challenges persist
Traditional Knowledge Databases	No comprehensive national TK database	Emerging databases inspired by India's TKDL to prevent patent misappropriation (Tambunan, 2023)	No centralised database, but documentation occurs through community and state initiatives
Remedies and Benefit-Sharing	Benefit-sharing required via mutually agreed terms (MAT), but limited judicial clarification on remedies	Contractual benefit-sharing mechanisms; state oversight in agreements	Statutory entitlement to equitable benefit-sharing, with stronger legal basis for community claims

4.5 Institutional and Policy Challenges in Malaysia

Despite legislative advances, several institutional challenges hinder effective implementation of Act 795:

1. **Fragmented Governance:** Federal-state jurisdictional divides create inconsistencies between national, Sabah, and Sarawak biodiversity regimes.
2. **Limited Community Involvement:** Indigenous participation often occurs at the consultation stage without real decision-making power.
3. **Lack of Enforcement Capacity:** Monitoring and sanctioning unauthorized bioprospecting remains difficult due to limited technical expertise and funding.
4. **Awareness Deficit:** Many local researchers and institutions are

unfamiliar with ABS requirements, resulting in inadvertent non-compliance.

5. **Intellectual Property Conflicts:** Patent offices still operate under IP frameworks that prioritize novelty and individual ownership, making integration with TK protection difficult.

Addressing these challenges requires not only administrative reform but also the reorientation of Malaysia's intellectual property and biodiversity governance toward a rights-based and community-centered approach.

4.6 Institutional Dimension: The Role of the Intellectual Property Corporation of Malaysia (MyIPO)

An important institutional gap in the current analysis is the limited consideration of Malaysia's national intellectual property authority, the Intellectual Property Corporation of

Malaysia. While the governance of biological resources and traditional knowledge is primarily addressed through biodiversity legislation particularly the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795) the role of MyIPO remains significant in shaping how intellectual property rights over bio-based innovations are examined, granted, and enforced.

From an institutional perspective, MyIPO administers Malaysia's patent, trademark, and copyright regimes in accordance with international standards, including the TRIPS Agreement. However, its current framework does not require patent applicants to disclose the origin of genetic resources or demonstrate compliance with access and benefit-sharing (ABS) obligations. This reflects a broader structural separation between intellectual property administration and biodiversity governance, a gap widely noted in the literature (Correa, 2021; Dutfield, 2011). As a result, patents may be granted for inventions derived from biological materials or traditional knowledge without verification of lawful access, thereby creating the risk of regulatory inconsistency.

The absence of formal coordination mechanisms between MyIPO and ABS authorities established under Act 795 further exacerbates this issue. While Section 12 of Act 795 requires prior informed consent (PIC) and Section 21 mandates mutually agreed terms (MAT), there is no statutory obligation for MyIPO to verify compliance with these provisions during patent examination. This institutional disconnect mirrors global concerns regarding the lack of “mutual

supportiveness” between the TRIPS framework and biodiversity instruments such as the Convention on Biological Diversity and the Nagoya Protocol (Morgera, 2020).

Engagement with MyIPO is therefore essential for institutional realism. As Drahos (2016) observes, intellectual property offices play a critical gatekeeping role in determining what constitutes legally protectable innovation. Without integrating biodiversity-related checks into patent procedures, domestic ABS regimes risk being undermined at the point of IP registration. Similarly, WIPO-led discussions on genetic resources have increasingly emphasised the need for national IP offices to incorporate disclosure of origin requirements and traditional knowledge databases into examination processes (WIPO, 2023).

From a policy perspective, incorporating MyIPO into the ABS framework would strengthen domestic governance in three key ways. First, it would enable cross-institutional verification, ensuring that patent applications involving biological materials are consistent with ABS permits issued under Act 795. Second, it would support the development of defensive protection mechanisms, such as traditional knowledge databases that can be used as prior art to prevent erroneous patent grants. Third, it would enhance enforcement coherence, allowing authorities to address biopiracy not only at the point of access but also at the stage of commercialisation.

These institutional considerations directly inform the reform proposals advanced in Section 6. In particular, the recommendation for mandatory disclosure of origin in patent

applications and the integration of ABS compliance checks within intellectual property procedures cannot be operationalised without the active involvement of MyIPO. Thus, recognising the role of the national IP authority is not merely descriptive but foundational to designing effective and implementable legal reforms.

METHODOLOGY

This study adopts a qualitative doctrinal legal research methodology supplemented by comparative and socio-legal perspectives. The doctrinal approach involves analysing primary legal sources such as international treaties (TRIPS, CBD, Nagoya Protocol, and UNDRIP), Malaysian statutes particularly the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795) and relevant case law. Secondary sources including journal articles, reports, and commentaries were reviewed to evaluate how legal norms have evolved in both international and Malaysian contexts.

The research also employs a comparative legal method, drawing parallels between Malaysia's ABS legislation and the frameworks of other biodiverse countries such as India, the Philippines, and Brazil. These comparisons provide insights into best practices and legal innovations in addressing biopiracy through community-based benefit-sharing.

A socio-legal lens complements the doctrinal framework by examining the lived realities of indigenous communities particularly the Orang Asli and native peoples of Sabah and Sarawak whose traditional knowledge often forms the foundation of commercial biotechnological products. Field-based findings from published ethnographic and environmental legal studies were integrated to highlight the gap between law in books and law in action.

Data sources were triangulated using academic journals (Scopus, Web of

Science, HeinOnline), government publications, and reports from intergovernmental organisations such as the World Intellectual Property Organization (WIPO) and the United Nations Development Programme (UNDP). This mixed-method legal analysis enables a nuanced understanding of how legal doctrine, institutional enforcement, and indigenous participation interact in addressing biopiracy.

LEGAL AND POLICY REFORM PROPOSALS

6.1 Strengthening the Domestic Legal Framework

Malaysia's Access to Biological Resources and Benefit Sharing Act 2017 (Act 795) is a significant milestone, but its implementation remains fragmented. The following reforms are proposed:

- Clarify federal state jurisdiction: Biodiversity governance overlaps between federal agencies (e.g., Ministry of Natural Resources and Environmental Sustainability) and state authorities. Harmonisation through a National ABS Coordination Council could streamline benefit-sharing processes and ensure equitable representation of indigenous groups.
- Integrate customary law: Indigenous customary systems (e.g., adat and native court principles) should be formally recognised as a source of law in determining ownership and benefit-sharing rights over biological materials.
- Expand enforcement mechanisms: Current penalties under Act 795 are administrative. Introducing civil remedies and community-based compensation schemes would enhance deterrence against biopiracy.

6.2 Recognising Collective Ownership and Indigenous IP Rights

Conventional intellectual property regimes particularly patent law are individualistic and time-limited. Indigenous knowledge systems, however, are collective, intergenerational, and continuous. Malaysia could consider adopting a sui generis protection system, similar to India's Traditional Knowledge Digital Library (TKDL), to document, preserve, and safeguard traditional knowledge against misappropriation.

Moreover, integrating Free, Prior, and Informed Consent (FPIC) procedures into patent and bioprospecting approvals would operationalise the principles of UNDRIP and Nagoya Protocol at the domestic level. This would ensure that communities retain control over how their biological and cultural resources are utilised.

6.3 Strengthening Regional and International Cooperation

ASEAN states could collaborate to establish a Regional Biodiversity and Traditional Knowledge Network, harmonising ABS frameworks and facilitating joint enforcement. Malaysia, as a biodiversity hub, could lead in promoting cross-border legal mechanisms for tracking genetic resources, preventing "forum shopping" by corporations seeking lenient jurisdictions.

At the international level, Malaysia should advocate for TRIPS reform through the mandatory disclosure of origin requirement in patent applications linking IP protection with biodiversity conservation. This alignment would balance innovation incentives with the principles of equity and sustainability.

6.4 Institutional and Educational Measures

To ensure the long-term sustainability of reforms:

- Establish a National Biodiversity Tribunal for dispute resolution

involving bioprospecting and benefit-sharing claims.

- Introduce capacity-building programs for indigenous communities to negotiate ABS agreements.
- Develop legal education modules on biodiversity law in Malaysian universities and judicial training institutes.

These steps would institutionalise awareness and build domestic expertise in biodiversity governance.

CONCLUSION

Biopiracy represents a contemporary form of knowledge colonialism, where the intersection of intellectual property law, biodiversity, and indigenous rights remains contested. International instruments such as the CBD, Nagoya Protocol, and UNDRIP provide a normative foundation, but domestic implementation particularly in Malaysia requires greater legal coherence and participatory governance.

This study finds that Malaysia's legal trajectory reflects both progress and limitation: the enactment of the ABS Act 2017 is commendable, yet the absence of comprehensive indigenous intellectual property protection and weak institutional coordination continue to hinder justice for native communities.

Moving forward, the integration of customary law, the establishment of clear benefit-sharing mechanisms, and regional collaboration under ASEAN frameworks are critical. A sui generis model of indigenous IP protection, grounded in collective ownership and equitable access, would not only deter biopiracy but also uphold Malaysia's constitutional commitment to protecting the cultural heritage of its indigenous peoples.

Ultimately, the fight against biopiracy is not merely a legal battle it is a pursuit of epistemic justice, affirming the right of communities to control, benefit from, and sustain their biological and cultural legacies.

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