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Patent Disclosure Requirements for Traditional Knowledge Associated with Genetic Resource: A Critical Analysis of WIPO Treaty, 2024

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The World Intellectual Property Organization (WIPO) recently adopted an important multilateral treaty establishing mandatory patent disclosure requirements (PDRs) for genetic resource and associated traditional knowledge. This treaty aims to prevent erroneous patent grants by ensuring that patent applicants disclose 'country of origin' of traditional knowledge and/or indigenous peoples or local communities providing such traditional knowledge. If such information is unknown, applicants must disclose the 'source of origin' to the relevant Patent Office, enhancing transparency, quality, and the overall efficacy of the global patent system. Despite its potential benefits, this treaty has drawn criticisms from experts for its vague and flexible provisions relating to source of origin when multiple countries or communities are involved, reliance on the patent applicant's best knowledge without independent verification, and availability of corrective measures in case of non-disclosure. This article critically examines this new WIPO treaty intersecting traditional knowledge and patentability, particularly its mandatory patent disclosure requirements for single or multiple patent application(s) in different jurisdictions. It argues that while this treaty marks a significant step in integrating patent rights with biodiversity protection, its inadequate and flexible provisions for disclosure requirements related to traditional knowledge associated with genetic resource limits the effective implementation.

Keywords: WIPO Treaty, Global Patent System, Patent Disclosure Requirement, Genetic Resource, Traditional Knowledge

The relationship between genetic resource, traditional knowledge, and intellectual property right has long been a highly debated issue in legal and policy arena for more than three decades. The unregulated access and unauthorised use of genetic resource (GR) and associated traditional knowledge (ATK) have sparked intense debates in multilateral negotiations. Indigenous communities and sovereign countries especially developing but biodiversity rich countries, have demanded for stronger intellectual property protection for traditional knowledge, cultural expression, and other traditional forms of creativity and innovation. Their efforts seek to protect the misappropriation and misuse of traditional knowledge and cultural expressions, which are often perceived as part of the public domain and vulnerable to unrestricted access and exploitation. The legal framework surrounding genetic resource and traditional knowledge is complex and involves several international treaties, policies and strategies. The 'Convention on Biological Diversity (CBD)'[1] and its 'Nagoya Protocol (NP)'[2] serve as key international legal instruments for regulating access to genetic resources and ensuring the fair and equitable sharing of benefits derived from their commercial utilization. Besides, the 'United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)' also plays a crucial role by recognizing indigenous peoples' rights to "maintain, control, protect, and develop their intellectual property over cultural heritage, traditional knowledge, and traditional cultural expressions."[3] Besides, the World Trade Organisation (WTO), through its "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)"[4] prescribed minimum standards and criteria for new and innovative inventions for product and process patent based on traditional knowledge, but fails to protect this knowledge directly. In response to these, the World Intellectual Property Organization (WIPO) adopted recently an important treaty as "*The WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge.*"[5] It is an important legal instrument in aligning intellectual property rights with biodiversity conservation by introducing mandatory patent disclosure requirements for genetic resource and associated traditional

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knowledge. Non-disclosure of origin or source has created problems or challenges of misappropriation, unauthorized use or exploitation, commercial utilization without sharing benefits, and bio-piracy for decades. This treaty now mandates that the patent applicants must disclose 'country of origin' or 'source of origin' of genetic resource and/or associated traditional knowledge provided by indigenous peoples or local communities if their invention is based on such resource or knowledge.[5]

Despite its potential benefits in enhancing transparency and preventing erroneous patent grants, this treaty has faced criticisms for its vague and flexible provisions. Key concerns include ambiguity in determining the source of origin when multiple countries or communities, reliance on the patent applicant's best knowledge without independent verification, and the availability of corrective measures in case of non-disclosure.[6] Furthermore, the treaty allows for flexible implementation by national compliance measures added with terms "as applicable" "appropriate" and "proportionate" potentially weakening its enforcement in domestic jurisdictions.[7] The treaty's effectiveness in preventing bio-piracy and ensuring fair benefit-sharing also remains debatable. This article aims to critically analyse this new WIPO Treaty focusing on its mandatory patent disclosure requirements for traditional knowledge associated with genetic resources. It argues that while this treaty marks a significant step in integrating patent rights with biodiversity protection, its inadequate and flexible provisions for disclosure requirements related to traditional knowledge associated with genetic resource limits the effective implementation at the national level. This article is structured into six parts: an introduction, traditional knowledge as the subject matter of patent protection, an overview of the new WIPO Treaty, a critical analysis of this WIPO Treaty, and a conclusion. Reviewing the existing literature and legal instruments, the authors employ doctrinal research method with descriptive and analytical approaches to find critical observations and findings.

Traditional Knowledge associated with Genetic Resources as Subject Matter of Patent

Traditional knowledge especially associated with genetic resources has been catalyst in the economic, social, and cultural development of communities and countries. Because of its evolving nature, 'traditional knowledge' has not been holistically and legally defined with consensus among the communities and countries. Herein, the term 'traditional knowledge' has been used to address knowledge, practice, and innovation associated with the genetic resources held by the indigenous peoples and local communities. WIPO considers traditional knowledge as "knowledge, know-how, skills, and practices that are developed, sustained and shared with generation to generation within a community, often forming part of its social, cultural or spiritual identity."[8] It has been practiced, preserved, and developed by indigenous peoples or aboriginals of different nations for generations. Being custodians and beneficiaries, they have also been legally recognized as rightful holder of such traditional knowledge who have identified, collected and preserved it with constant trails and errors from ambient flora and fauna in the nature. Not only this, "ATK has always remained part of their life, culture, traditions, beliefs, arts, and folklore, covering a broad spectrum of traditional lifestyle, agriculture, medicine, and other spheres of human activity."[9] It has also been recognized as "intangible property which is being utilized for the commercial benefits by providing valuable leads to bio-prospecting for development of new and useful product and process."[10] Research institutions, universities and industries such as food, beverages, pharmaceuticals, chemicals, cosmetics, horticulture, and agriculture have tried to access it for its commercial and non-commercial utilization.[11] This commercial prospect and use has increasingly led to the appropriation and misappropriation of such traditional knowledge by developed or industrialized nations. Consequently, there has been reported instances of violation of legal rights and non-sharing the monetary or non-monetary benefits with rightful holders of such traditional knowledge.[12] It has been rightly observed that "the intersection of traditional knowledge and biomedical innovation has given birth to new patents on the products and processes avoiding the benefits and rights to the rightful holders of the traditional knowledge"[13] which has necessitated legal protection of traditional knowledge under intellectual property legal regime. Under this regime, patent has been considered the most suitable legal regime for "providing exclusive rights and protection through 'positive' and 'defensive' protection to such knowledge, innovations, and practices."[14] Both the protections provided under this legal regime may be analyzed as follow:

Positive Protection

Positive measure or protection is provided to such traditional knowledge by considering it inherently patentable subject matter as an invention or innovation, without falling it in any prescribed exception and disqualification. The exclusive or monopoly rights are provided to rightful owner or holder of traditional knowledge for commercial utilization and industrial application for a specific period. In other words, "it confers on the patent holder the right to exclude others not having the patent holder's consent form doing or making anything that falls within the subject matter of invention as defined and bounded by the patent claims."[15] Instead of this, the patent holders or applicants have to disclose the invention based on traditional knowledge in a sufficient manner to the person with skill in the art/knowledge or respective national patent authorities.[16] It becomes part of conventional patent disclosure as a "bargain" for the disclosure of invention by them in exchange for legal or patent protection for a limited period. Further, patent offices and authorities are empowered to examine the information provided or disclosure made on the patent claims or applications for new inventions or innovations based on such traditional knowledge.

Defensive Protection

Defensive measure or protection refers to "a set of strategies to ensure that third parties do not gain illegitimate or unfounded IP rights over traditional knowledge."[17] Under the defensive measures, two protective options are suggested against misappropriation of traditional knowledge as: "'disclosure of origin' regarding the subject matter of the patent application; and recognition as 'prior art' to establish novelty in a patent application."[18] For this purpose, it is necessarily required that traditional knowledge be recognized and made available to the patent offices across the countries; develop the information system and data system after publication and registration of the traditional knowledge; and empower patent authorities to examine the patent application after verifying existing digital resources and published information related to such traditional knowledge.

At national level, "several nations have introduced these defensive measures in their national laws requiring specific forms of disclosure relating to traditional knowledge and genetic resources used in the claimed invention."[19] At the international level, WIPO, through the General Assembly, has also established the Intergovernmental Committee (IGC) to prepare international legal instruments for the protection of genetic resources and traditional knowledge since the year 2000. As an outcome of international negotiations under the auspicious of WIPO IGC after twenty-five years, the new "WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge" was adopted at the Diplomatic Conference in Geneva on May 24, 2024.

The WIPO Treaty, 2024: An Overview

This WIPO Treaty marks a key milestone in international efforts to navigate the complex interplay between intellectual property rights, biodiversity, and traditional knowledge. The treaty's development involved extensive negotiations, reflecting a global commitment to ensuring that the use of genetic resources and traditional knowledge is fair, transparent, and beneficial to all parties involved. This part offers a broad overview of the treaty, including its negotiation history, main objectives, and key provisions that aim to enhance transparency and prevent the misappropriation of genetic resources and traditional knowledge.

Background and Development of the Treaty

The relationship between intellectual property right and indigenous culture or knowledge has evolved significantly over the years. Early international efforts in this regard date back to the "1967 revision of the Berne Convention for the Protection of Literary and Artistic Works (Stockholm)."[20] It took another three decades to give a formalized structure with the establishment of 'WIPO Intergovernmental Committee (IGC)' in the year 2000. Afterwards, the WIPO IGC played a crucial role in shaping international perspectives on genetic resources, associated traditional knowledge, and traditional cultural expressions. Over two decades, the WIPO IGC facilitated negotiations that transformed the perception of GR and ATK from being part of the common heritage of mankind to valuable assets susceptible to protection by the IP system.[21] The WIPO IGC's efforts culminated in development of a draft instrument that was presented at a diplomatic conference. The WIPO General Assembly resolved to hold this conference in July 2022, leading to the "Diplomatic Conference in Geneva from May 13-24, 2024."[22] This conference resulted in adoption of the

'*WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge'*, marking a significant milestone in international cooperation and multilateral negotiation. The treaty's development reflects a global commitment ensuring that the use of genetic resources and traditional knowledge is fair, transparent, and beneficial to all parties involved. It builds upon earlier international frameworks, such as the CBD and the Nagoya Protocol, which established principles for 'access to genetic resources' and the 'fair and equitable sharing of benefits' arising from their commercial use.[23] The history of WIPO treaty's negotiation highlights the challenges and complexities involved in balancing the interests of developed and developing countries. While developing countries advocated for legally binding instruments to protect against the misappropriation of genetic resources and traditional knowledge, but developed countries favoured more flexible and non-binding approaches towards it. Now, the treaty reflects a compromise between these two aspirations and perspectives, aiming to enhance transparency and prevent the misuse of genetic resources and traditional knowledge while facilitating innovation, development and investment in globalized world.

Main Objectives of the Treaty

It has two primary objectives[24]: *firstly,* it seeks to improve the effectiveness, transparency, and integrity of the patent system by ensuring that patents are granted only for genuinely novel and inventive inventions, especially those involving genetic resources and traditional knowledge. This shall be achieved through mandatory disclosure requirements to prevent erroneous patent grants. *Secondly*, the treaty aims to prevent the granting of patents for inventions that lack novelty or inventiveness concerning genetic resources and associated traditional knowledge. By mandating that patent applicants disclose the country of origin of genetic resources and identify any indigenous peoples or local communities providing associated traditional knowledge, the treaty helps ensure that inventions are legitimately derived from these resources and knowledge.[6] These objectives are essential for ensuring fairness and transparency in the utilization of genetic resources and traditional knowledge, fostering innovation, development and investment while upholding the rights of indigenous peoples and local communities. The treaty's provisions for disclosure and benefit-sharing with source communities are also aligned with objectives and mandates of CBD and NP, promoting fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge.

Key Features of the Treaty

The treaty is structured around twenty-two important provisions that provide definitions, outline disclosure obligations, and set enforcement mechanisms, all of which are crucial for ensuring fair and equitable treatment of genetic resources and associated traditional knowledge with genetic resources. To provide clarity on its scope and application, the treaty defines key terms that are essential for interpreting its provisions. 'Genetic resources' are defined as "any genetic material of actual or potential value."[25] However, it does not define the term 'traditional knowledge associated with genetic resources.' But this treaty clarifies what constitutes a 'source' of GRs and ATK. The source of genetic resources refers to "any entity from which an applicant has obtained the material, such as research institutions, gene banks, indigenous communities, or *ex-situ* collections."[25] Similarly, the source of ATK refers to "any documentation, oral transmission, publicly available databases, or other records where traditional knowledge is found."[25] The treaty ensures that patent applicants acknowledge the origins of these materials to promote transparency in the patent system. The term **'**based on**'** is crucial in determining the applicability of this treaty. An invention is considered **'**based on genetic resources or traditional knowledge' if the GRs or ATK has served as the necessary basis for the claimed invention and if the claimed invention depends on the specific properties of the GRs and/or the ATK.[26] This means that an invention must derive substantial and direct contributions from GRs or ATK to trigger patent disclosure requirements. The other main features of this treaty have been outlined as follows:

i) *Mandatory Patent Disclosure Requirements:* A key component of this treaty is its mandatory disclosure requirement which obliges patent applicants to provide specific details regarding the genetic resources and associated traditional knowledge used in their inventions. When filing a patent application that is based on genetic resources, the applicant must disclose the country of origin of the genetic resource or, if the country of origin is unknown, the source from which it

was obtained.[27] Similarly, if the invention is based on traditional knowledge, the applicant must disclose the indigenous peoples or local communities that provided the knowledge or, if unknown, the source from which the traditional knowledge was obtained.[26] This disclosure requirement ensures that indigenous communities and source countries are recognized for their contributions and prevents the granting of patents based on misappropriated genetic resources or traditional knowledge. However, if the applicant genuinely does not know the required information, they are allowed to submit a declaration stating that they lack such knowledge.[28] Importantly, patent offices are not obligated to verify the authenticity of these disclosures, instead they are encouraged to provide guidance to ensure compliance.[29] By introducing mandatory disclosure requirements, the treaty basically seeks to prevent the misappropriation of traditional knowledge and enhance legal certainty in the global patent system.

ii) *Non-Retroactivity*: The treaty includes a non-retroactivity clause which states that its disclosure obligations do not apply to patent applications filed before the treaty enters into force for a particular country.[30] This provision is crucial because it ensures that the treaty does not retroactively impose new legal obligations on existing patents or pending applications. Instead, it provides legal certainty to patent applicants and respects national laws that were in place before the treaty's adoption.

iii) *Sanctions and Remedies:* A stand-out provision of the treaty is related to sanctions and remedies for non-compliance with the disclosure requirements. It requires "Contracting Parties to implement appropriate, effective, and proportionate legal, administrative, and/or policy measures to address non-compliance with disclosure requirements."[31] Before imposing sanctions, applicants must be given an opportunity to rectify any omissions. Further, it provides that except in cases of fraudulent intent, patents shall not be revoked or rendered unenforceable solely for failure to disclose required information.[32] However, it also allows Contracting Parties to impose post-grant sanctions or remedies in cases where fraudulent intent is established in accordance with national laws.[33] It is important to note that the treaty does not allow the invalidation or revocation of a granted patent solely on the basis of failure to disclose unless fraud is involved. These provisions ensure that patent holders are not unfairly penalized for unintentional omissions, but also establish a safeguard against deliberate misrepresentation.

iv) *Establishment of Information Systems:* The treaty allows contracting parties to develop information systems, such as databases of GRs and ATK.[34] These databases can help track the origin and use of GRs and ATK helping them to determine whether a claimed invention is genuinely novel or if it relies on pre-existing traditional knowledge. The establishment of such systems is encouraged to take place in consultation with relevant stakeholders, including indigenous peoples and local communities.[35] This ensures that the systems are designed to meet the needs of all parties involved and respect the cultural and traditional knowledge of the communities.[6] By providing a structured framework for managing and disclosing the use of GRs and ATK, these systems can help prevent misappropriation and ensure that benefits are shared equitably among all stakeholders. The treaty does not mandate the establishment of these systems, but rather encourages their development. This flexibility allows countries to adopt the treaty's provisions to their specific needs and technological capabilities, ensuring that the systems are effective and sustainable in practice.[36]

v) *Review Mechanism and Future Considerations:* To ensure that the treaty remains effective and adaptable to emerging challenges, it includes an in-built review mechanism. Four years after the treaty comes into force, a formal review will take place to assess key issues including whether the disclosure requirement should be expanded to other intellectual property areas and cover genetic resource derivatives.[37] The review process will also consider technological developments that may impact the implementation of treaty, such as digital sequence information (DSI) and synthetic biology.[38] This review will enable the examination of various issues, including the potential extension of disclosure requirements to other areas of intellectual property and addressing challenges posed by new and emerging

technologies.[39] This could involve extending disclosure requirements to derivative products or other forms of intellectual property ensuring that the treaty remains effective in preventing the misappropriation of GRs and ATK. The review mechanism allows for flexibility in adapting the treaty to changing circumstances. This is particularly important given the rapid pace of technological advancements and the evolving nature of intellectual property issues related to GRs and ATK.[6]

The WIPO Treaty represents a significant advancement in promoting fair and transparent recognition of genetic resources and traditional knowledge within the patent system. By requiring mandatory disclosure; establishing sanctions for non-compliance; and promoting information-sharing mechanisms and review mechanisms, treaty enhances legal framework for protecting ATK and its custodians, the indigenous and local communities. While flexibility was necessary for consensus, the treaty's vague language and flexible obligations may limit its impact and implementation. Hence, this treaty warrants a closer critical examination also.

The WIPO Treaty, 2024: A Critical Analysis

This WIPO Treaty represents a significant advancement in addressing the intersection of intellectual property, genetic resources, and traditional knowledge. However, despite its features, the treaty faces several criticisms regarding its effectiveness in protecting traditional knowledge and genetic resources. The treaty's definition clause has faced criticism for its ambiguities and legal uncertainties. One of the primary concerns is the ambiguity in terms such as 'based on', 'source', and 'country of origin.' It defines 'country of origin' as "the country which possesses those genetic resources *in situ* conditions."[25] This definition may not fully address the complexities of modern biotechnology particularly with the increasing use of DSI, which often has unclear or undefined geographical origins.[6] Another concern is the lack of precise definition and criteria to distinguish traditional knowledge that qualifies for patent protection. This treaty does not establish clear parameters on what constitutes 'associated traditional knowledge*'*, whether it must be documented, orally transmitted, or widely known within indigenous communities.[40] This uncertainty could lead to disputes over whether specific knowledge falls within the treaty's scope, undermining its practical enforceability. Additionally, the treaty fails to adequately define 'misappropriation', 'prior informed consent' and 'benefit-sharing' for genetic resources and associated traditional knowledge.[7] Without a precise legal definition, patent offices and courts may struggle to determine whether a violation has occurred leaving the system vulnerable to conflicting interpretations. This ambiguity not only weakens the treaty's effectiveness, but also creates potential loopholes to exploit GRs and ATK without facing clear legal consequences.

While these terms are central to treaty's objectives, the vague language allows contracting states to adopt their own interpretations leading to fragmentation in implementation. This treaty allows for flexible implementation by national compliance measures added with terms "as applicable" "appropriate" and "proportionate". These flexibilities could result in weaker protections in several jurisdictions with less stringent regulations, thereby undermining the treaty's intended global standard. Developing nations which are rich in genetic resources and traditional knowledge are particularly concerned about its implications.[41] The lack of clear definitions and robust enforcement mechanisms may hinder their ability to ensure proper recognition and compensation for their genetic and natural resources. Without more precise definitions, treaty may fail to achieve its goals of preventing bio-piracy; ensuring fair benefit-sharing; and harmonizing international patent disclosure requirements.[6] This could result in inconsistent application of the treaty across different jurisdictions, as countries may interpret these terms differently. Critical aspects of its specific features have been outlined as follows:

(i) *Flexible Patent Disclosure Requirement***:** One of the primary concerns in the treaty's patent disclosure requirement is the ambiguity and flexibility. The relevant provisions mandate the disclosure of the country of origin and the indigenous peoples or local communities providing traditional knowledge. However, it also allows applicants to submit a declaration if they lack this information without requiring due diligence to verify the sources. It creates a loophole where applicants can avoid disclosing essential information by claiming ignorance potentially undermining the treaty's objectives.[42] This treaty does not mandate patent offices to

verify the authenticity of disclosed information, which could lead to false or incomplete disclosures going unchecked. This non-obligatory clause for verification can provoke applicants to mislead the system, which is detrimental to the intellectual property rights of indigenous peoples. Furthermore, this treaty does not provide for patent revocation in non-disclosure cases unless fraudulent intent is proven.[42] This limitation diminishes the enforceability of compliance and fails to address the long-standing problem of bio-piracy effectively. Opponents of this treaty argue that the new disclosure obligations could impede innovation by creating uncertainty for patent applicants, investors, and the research and development sector.[43] Besides, it would carry the risk of facilitating the legalization of erroneous patents if not properly implemented. This could lead to an increase in number of declarations, making it more challenging for developing nations to monitor and ensure proper recognition and compensation for their genetic resources and associated traditional knowledge.

(ii) *Ambiguous Non-retroactivity Clause:* This new WIPO Treaty includes a non-retroactivity clause stating that its obligations do not affect patent applications submitted prior to the treaty's implementation.[44] The purpose of this clause is to ensure that new restrictions are not retroactively imposed on existing patents and applications. While it seeks to protect the rights of those who have already filed patent applications, it also introduces significant challenges that could undermine the treaty's objectives. One immediate consequence of the non-retroactivity provision is the possibility of a surge in preemptive patent filings.[45] Companies anticipating the treaty's implementation may rush to submit patent applications to avoid compliance with forthcoming mandatory disclosure requirements. Additionally, the treaty fails to provide protection for the intellectual property rights of indigenous communities who's ATK has already been exploited without their consent or proper recognition. Critics argue that by not addressing patents granted prior to the treaty's implementation, the non-retroactivity clause leaves existing patents which may have been erroneously granted without proper disclosure of GRs and ATK, unchallenged.[7] Furthermore, the treaty's non-retroactivity may conflict with national laws that have more stringent disclosure requirements.[46] For instance, India's Patents Act in conjunction with the Biological Diversity Act mandates disclosure of the origin of biological resources and ATK with provisions for retroactive cancellation of patents if these obligations are violated.[47] Implementing the WIPO treaty's non-retroactivity clause could, therefore, pose challenges for countries with more robust legal frameworks for protecting GRs and ATK.

(iii) *Ineffective Sanctions and Remedies:* The WIPO Treaty introduces a framework requiring the mandatory disclosure of traditional knowledge in patent applications. However, its provisions for sanctions and remedies remain a significant point of contention. The treaty delegates enforcement mechanisms to national laws, failing to establish a uniform international standard for non-compliance.[48] The lack of robust sanctions and the inability to revoke patents solely for non-disclosure undermine the treaty's effectiveness in protecting indigenous peoples and local communities.[41]This treaty explicitly states that failure to disclose the origin of traditional knowledge cannot be the sole basis for revoking a patent.[49] Instead, applicants are given an opportunity to rectify the omission unless the non-disclosure is proven to be fraudulent, in which case discretionary revocation is permitted.[50] This approach prioritizes legal certainty for patent holders while neglecting the fair and equitable benefit-sharing principles outlined in the CBD.[7] By deferring remedies to domestic legislation rather than embedding them in the treaty itself, WIPO has missed an opportunity to align intellectual property law with biodiversity conservation objectives. Another significant loophole in the treaty is the vague language regarding sanctions.[46] One of provision states that penalties for non-compliance should be 'appropriate, effective, and proportionate', but it does not specify what these penalties should entail.[51] This omission allows for disparities in enforcement across different jurisdictions. For example, a country with stringent patent laws may impose substantial fines or even cancel patent rights for non-compliance, while economically weaker nations with law enforcement mechanisms could become 'patent havens'

attracting companies seeking to bypass stricter regulations.[46] This disparity weakens the treaty's ability to prevent misappropriation and could encourage forum shopping, where patent applicants will strategically register patents in jurisdictions with minimal enforcement.

(iv) *Unbaked Information Systems:* This WIPO Treaty introduces provisions for an information system aimed at improving transparency and compliance with disclosure requirements.[52] The successful implementation of the WIPO Treaty's information system relies on the development of extensive databases documenting GRs and ATK. However, such databases are currently lacking which raises concerns about the system's effectiveness.[53] Without well-structured and reliable data repositories, patent offices and relevant authorities may struggle to ensure that disclosures align with the treaty's objectives. The absence of these foundational resources creates a risk that the information system will remain incomplete or fragmented limiting its usefulness for preventing bio-piracy. One of the primary concerns regarding the proposed information system is the lack of robust safeguards to prevent the unauthorized use of ATK. While the system is intended to provide publicly accessible information on GRs and ATK, it does not adequately address how sensitive traditional knowledge will be protected from misuse. This treaty does not explicitly require free, prior, and informed consent (FPIC) from indigenous communities before their knowledge is added to the database, leaving them vulnerable to exploitation. If companies and researchers can easily access this information without needing direct consent from indigenous groups, there is a risk that the database will be used as a resource for patent filings rather than as a tool for preventing misappropriation.[7]

Given the history of bio-piracy, where corporations and researchers have accessed ATK without consent or fair compensation, the risk of the database being exploited for commercial gain remains high. The treaty does not establish clear mechanisms for indigenous peoples to control how their knowledge is shared, raising concerns that the system could become a tool for misappropriation rather than protection.[41] The treaty does not provide adequate mechanisms to ensure indigenous communities have direct control over their knowledge or to address challenges related to language barriers, digital literacy, and connectivity in remote areas.[46] Many indigenous groups face digital and infrastructural barriers, limiting their ability to engage with and benefit from the information system. Without meaningful access, the system risks serving the interests of corporations and researchers rather than the communities it is supposed to protect. The treaty does not empower patent officials to verify the accuracy or authenticity of disclosed GRs and ATK, which could lead to unreliable or misleading entries in the system.[41] Without a verification mechanism, the effectiveness of the information system as a tool to prevent wrongful patent claims is severely weakened.

(v) *Review Mechanism and its Uncertainty:* This WIPO Treaty includes a review mechanism designed to address emerging issues and ensure the treaty's effectiveness. This mechanism mandates a review four years after the treaty's entry into force focusing on extending disclosure requirements to other intellectual property areas and addressing new technologies. The flexibility in the review period allows it to be delayed beyond four years, providing room for adjustments based on evolving global needs.[6] It requires ratification by fifteen parties to enter into force, and as of May, 2025 only Malawi had ratified it.[54] While the treaty is seen as a positive step toward inclusivity, its abstract provisions might limit its concrete impact unless effectively implemented. Recommendations for future enhancements include accelerating the initial review period, implementing tiered sanctions and incentives for compliance, and establishing minimum standards for information systems.[55] The treaty's flexibility lowers the disclosure requirement and allows countries to implement it in different ways, leading to inconsistencies and legal risks.[54] In the coming years, ratifications and domestic implementation will reveal how effective these compromises are in practice. The review mechanism highlights the need for ongoing evaluation and adaptation to ensure the treaty's effectiveness in promoting transparency and fairness in the global patent system.

These shortcomings highlight key areas for future research and development in coming days. Studies should focus on standardizing definitions to enhance legal clarity, evaluating national disclosure

frameworks to strengthen compliance, and assessing the role of digital sequence information in benefit-sharing. Additionally, examining the political and economic factors affecting treaty ratification could offer insights into improving global cooperation and enforcement.

Conclusion

This new WIPO Treaty aims to address the intersection of intellectual property rights, genetic resources, and traditional knowledge. However, despite its vital objectives and distinct features, this treaty faces critical challenges that may weaken its effectiveness in protecting traditional knowledge associated with genetic resources. The treaty's definition clause lacks clarity, leaving key terms such as 'based on', 'source', and 'country of origin' open to interpretation. Without clear definitions of traditional knowledge, misappropriation, prior informed consent, and benefit-sharing, the treaty risks inconsistent enforcement across jurisdictions. Traditional knowledge is often held collectively by a community, making it difficult to identify a specific 'provider' among them for the purpose of disclosure requirements. The treaty's requirement to name the indigenous peoples or local communities might also be challenging when knowledge is shared across a broader group or passed down through generations without a specific point of origin. The treaty mandates disclosure of the country of origin of traditional knowledge and the indigenous groups providing it, but it also allows applicants to disclose information through a simple declaration. Furthermore, patent offices are not even obligated to verify the accuracy of such disclosed information. This does not guarantee that the disclosed traditional knowledge will be respected or that benefits will be shared if the patent is granted. Therefore, without stringent enforcement mechanisms or penalties for non-disclosure, the treaty could fail to deter unauthorized use of traditional knowledge.

Besides, the non-retroactivity clause exempts patents filed before the treaty's enactment, allowing prior cases of misappropriation to remain unchallenged. It could also encourage companies to file patents before the treaty takes effect to avoid compliance. The treaty relies on national governments for enforcement, which leads to inconsistent sanctions across nations. Patent revocation is not allowed solely for non-disclosure unless fraud is proven to reduce accountability. Not only this, the proposed information system aims to enhance transparency, but lacks comprehensive databases for GRs and ATK. Also, many of indigenous communities face digital access barriers limiting their ability to engage with this information system. A review mechanism is set for four years after the treaty's enactment, but delays in ratification pose challenges in effective implementation. In this way, it is observed that this new WIPO Treaty marks a significant step in integrating patent protection with biodiversity conservation, but its inadequate and flexible provisions for disclosure requirements related to traditional knowledge associated with genetic resources limit the effective implementation at the national level. Strengthening the treaty requires clear definition, stricter enforcement, and global cooperation to ensure uniform disclosure requirement and benefit-sharing is essentially required. Future efforts should lead to adequate and mandatory disclosure of traditional knowledge, independent and regular enforcement oversight, multi-tiered sanctions, and standardized information systems. Without these improvements, the treaty risks becoming a symbolic gesture rather than a meaningful step toward the defensive protection of traditional knowledge under the global patent system.

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