WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

Balancing Competing Interests to a Landmark Achievement*

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The journey to the WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge[1] has spanned nearly a quarter of a century.[2] After years of negotiations in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), the Treaty's final text was agreed upon on 24 May 2024, marking a historic achievement. The Treaty represents a small step, although an important one, towards defensive protection of traditional knowledge (TK) from Indigenous Peoples and Local Communities (IPLCs) and the sovereignty of WIPO's Parties over their genetic resources (GR). It addresses the need for greater transparency in the use of GR and TK, especially in light of the rapid advancement of biotechnology and the ready availability of genetic information in databanks, such as gene banks, as well as the increased development of new technologies that still rely heavily on the "shortcuts" provided by TK.



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The Treaty was born within the political context of Access and Benefit Sharing (ABS), shaped by competing and divergent interests: the Global North, predominantly biodiversity-poor and technology-rich, supports the free exchange of resources and information to fuel innovation and technological advancement. In contrast, the Global South, which is mainly biodiversity-rich and technology-poor, advocates for compliance with their sovereign rights by ensuring abidance to ABS regulations and by guaranteeing fair and equitable sharing of benefits arising from the use of GR and associated TK.[3]

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (CBD) provides the framework for ABS.[4] It mandates that countries ensure compliance with ABS regulations, requiring transparency for its implementation.

The recently adopted WIPO Treaty introduces a critical provision: the requirement for the disclosure of origin in patent applications. Ideally, to maximise the effectiveness of this provision, the trigger for disclosure should align with the trigger for ABS requirements, which is the defined and agreed-upon concept of "utilization." "Utilization of genetic resources"[4] means to conduct research and development on the genetic and/or biochemical composition of GR, including through the application of biotechnology as defined in Article 2 of the CBD.[5] A consistent trigger for both ABS and IP disclosure would ensure coherence in legal frameworks, enhanced transparency, juridical certainty for users of GR and TK as well as the possibility of streamlined administrative processes for patent offices and ABS authorities.

However, the Parties' decision to use the expression "based on" as the trigger for the disclosure presents significant challenges. "Based on" means *"that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary for the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or on the traditional knowledge associated with genetic resources"*.[1] This phrasing introduces ambiguity and limitations compared to the more comprehensive "utilization" trigger, as it provides a more restrict scope and does not provide clarity as "specific properties" has no definition within the text. How efficiently this scope will function to prevent misappropriation is still to be proved.

The National Institute of Industrial Property (INPI), which functions as the Brazilian patent office, already has mechanisms in place for the disclosure of compliance with Law 13,123, of 2015, regulating access and benefit sharing regarding genetic heritage. Presently, this requirement only applies to genetic information from organisms found *in situ* or that have acquired distinctive properties within Brazil. However, with the adoption of the new Treaty, INPI will need to expand this disclosure requirement to include the origin or source for all genetic resources on which a patent may have been "based on", including those exotic to Brazil.

Digital sequence information (DSI) refers to genetic information stored and shared in digital formats. It includes nucleotide sequences, amino acid sequences, and related information used in genomics, biotechnology, and other fields.[6] Decision 15/9[7], adopted at the 15th meeting of the Conference of the Parties (COP 15) to the CBD, addressed the issue of DSI on GR within that Convention and its Protocols. It outlined several provisions regarding the use and governance of DSI, but mainly, the decision reaffirmed the commitment to the benefit-sharing principle when DSI is used. This decision adds complexity and urgency to the need for clear and enforceable requirements for the disclosure of the origin of GR and TK in patents and other forms of IP since DSI can be easily copied, shared, and transmitted across borders, making it challenging to track the origin of the genetic information and ensure compliance with ABS. Without such requirements, ensuring that the benefits derived from using DSI are shared with the rightful owners becomes arduous.

Several stakeholders, especially from provider countries and IPLCs, have criticised the exclusion of DSI within the trigger for disclosure in Article 3 of the new Treaty.[8] However, DSI is not excluded from the scope of the WIPO Treaty, as evidenced by the inclusion of gene banks as a source of GR within the Treaty's list of terms. Gene banks increasingly utilise DSI to catalogue and share genetic information and by explicitly referencing them as a potential source for the obtention of GRs, the Treaty has acknowledged the contemporary practices of using genetic data from *in silico* sources.

Moreover, Article 8 allows the review of the scope and the trigger, leaving room for future decisions on DSI by the CBD to shape a proper approach for dealing with DSI within WIPO. Once the CBD determines how to address the use and benefit sharing of DSI, these guidelines should be integrated into the WIPO Treaty through the review article for consistency, legal certainty and predictability.

Another concern for provider countries and IPLCs is that the phrasing of Article 5 might incentivise misappropriation, as it limits the possibility of revoking a conferred patent for failing to provide disclosure of origin. Suppose sanctions for non-disclosure are not stringent enough compared to the potential benefits to be gained from patenting inventions derived from GR and TK. In that case, entities might calculate that the cost of any imposed sanctions for non-compliance is much lower than the financial and competitive advantages secured through the patent. It may create a scenario where the risk of non-disclosure and misappropriation becomes an economically viable strategy, effectively encouraging entities to bypass benefit-sharing obligations to the detriment of the rights of IPLCs and hindering efforts to reverse biodiversity loss.

Additionally, requiring Parties to prove fraudulent conduct in cases of non-disclosure places an onerous burden on providing Parties and TK holders, especially when TK has been widely disseminated or diffused over time. Proving fraudulent intent demands concrete evidence that the patent applicant intentionally misrepresented or omitted the origin information, a task complicated by TK's informal and communal nature, often published without consent.[9] The difficulty in proving fraudulent conduct may weaken the enforcement of disclosure requirements, potentially allowing misappropriation to go unpunished and undermining the overall efficacy of the Treaty in safeguarding TK.

INPI, as established by Law 13,123, of 2015, may not grant a patent if it fails to comply with ABS requirements in Brazil. As this checking step is adopted prior to a patent being conferred, Law 13,123, of 2015 still provides an effective mechanism for the protection of associated TK from misappropriation, despite any fragility that might exist considering Article 5 of WIPO´s new Treaty. In fact, the introduction of the word "conferred" was an effort by Global South parties to maintain the ability of Parties not to grant a patent if it fails to disclose the origin or source of GR or TK.

One major contention within IGC negotiations has been the call for an international Treaty to provide *sui generis* protection for GR and TK. Such a *sui generis* framework would recognise the intrinsic value and distinct nature of TK and traditional cultural expressions (TCEs), offering a solution that proactively recognised and preserved this knowledge, guaranteeing rights to its holders.[10] Despite longstanding calls for a *sui generis* system, the adopted WIPO Treaty falls significantly short of this objective: it primarily offers defensive protection through its disclosure requirement. Addressing unresolved and cross-cutting issues, as well as considering options for a draft legal instrument for TK and TCEs, remains on IGC`s mandate for 2024-2025.[11]

Notwithstanding the many shortcomings, the outcome of the WIPO Treaty should still be considered a success since it represents a step forward by incorporating TK directly into the WIPO framework and, by extension, the global intellectual property system. Prior to this Treaty, TK protection was indirectly addressed through environmental agreements such as the CBD and the Nagoya Protocol. These agreements, while important, could not integrate TK into the global IP regime, leaving it on the periphery of international intellectual property law. In conclusion, the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge lays a foundation for the efficient protection of GR and TK, fostering a more inclusive and biodiversity-friendly global IP system. Continued collaboration and refinement of the Treaty's provisions will be essential to fully realise its potential and achieve a fair balance between the interests of biodiversity-rich and technology-rich nations, as well as TK holders.

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