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C O M M E N T

INTELLECTUAL PROPERTY, GENETIC RESOURCES, AND ASSOCIATED TRADITIONAL KNOWLEDGE

by N.S. Gopalakrishnan, Srividhya Ragavan, and Narendran Thiruthy

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The relationship between the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) regime under the World Trade Organization (WTO) is complex. The manner in which intellectual property rights (IPRs) pertaining to genetic resources (GRs) and associated traditional knowledge (ATK) are handled is the main source of this dissonance.¹ The biodiversity framework recognizes the importance of IPRs but seeks to ensure they do not undermine the rights of countries that provide GR/ATK. On the other hand, the TRIPS-based IP regime emphasizes protecting IPRs but does not fully address the concerns of developing countries in this area.²

Various efforts have been made to reconcile the biodiversity and trade regimes, including the World Intellectual Property Organization (WIPO) establishing its Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore. Over the past two decades, the IGC negotiated for protection of traditional knowledge (TK) and traditional cultural

expressions (TCEs), including for creation of strong disclosure requirements and positive protection. Such efforts included addressing the disclosure of country of origin of GR/ATK to create a database to ensure creating a library of applicable prior arts. The negotiations have now culminated in a treaty, adopted in the WIPO Diplomatic Conference held in May 2024.³

Historically, creating an international binding obligation to prevent misappropriation of TK has been one of the most contentious issues for over two decades. The proponents of a binding obligation, primarily countries rich in ATK, have demanded both *positive* and *defensive* protection for TK. Positive protection envisages *sui generis* protection to prevent misuse or misappropriation of the existing TK, while defensive protection is intended to promote attribution to such knowledge when creating private rights using the IPR regime to prevent misappropriation. The IGC set up by WIPO has, for the past two decades, negotiated two international instruments for positive protection of TK and TCEs; and another for defensive protection of TK associated with GRs.⁴

While the most important international instruments for *sui generis* protection remain pending with the IGC, the WIPO Diplomatic Conference on May 24, 2024, concluded the WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge (WIPO GRTK Treaty).⁵ The treaty arguably provides defensive

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1. World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, *Revised Version of Traditional Knowledge: Policy and Legal Options*, U.N. Doc. WIPO/GRTKF/IC/6/4 Rev. (Feb. 19, 2004).
2. N.S. Gopalakrishnan, *TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System*, 27 EUR. INTELL. PROP. REV. 11 (2005).

3. Press Release, WIPO, WIPO Member States Adopt Historic New Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge (May 24, 2024) (PR/2024/919).
4. See WIPO, *Intergovernmental Committee (IGC)*, <https://www.wipo.int/tk/en/igc/> (last visited Aug. 7, 2024) (collecting documents on discussion in the WIPO IGC).
5. See also WIPO, *Basic Proposal for an International Legal Instrument Relating to Intellectual Property, Genetic Resources, and Traditional Knowledge Associated With Genetic Resources*, U.N. Doc. GRATK/DC/3 (Dec. 14, 2023); see also WIPO GRTK Treaty, U.N. Doc. GRATK/DC/7 (May 24, 2024)

protection to promote attribution when granting patent protection to GRs and TK associated with GRs. While the outcome has not fully addressed the demands of traditional communities, it is, in a limited way, a step forward to prevent misattribution of GR/ATK, particularly using the patent system.

The substance of the WIPO GRTK Treaty provides for disclosure requirements regarding the source and origin of the GR/ATK to create a database, but allows individual nations to have the flexibility to address situations of noncompliance and to consider providing remedies or sanctions.⁶ This Comment traces the history of the negotiations and discusses its impact on developing nations, taking India as a particular example. In doing so, it asserts that the final treaty is a great first step, but many critical issues related to GR/ATK have been left unaddressed. Thus, we suggest measures that the developing world can possibly adopt to better protect its interests within the treaty's framework.

I. Negotiating History of the WIPO IGC

The first time the international IP forums addressed the relationship between IPRs and Indigenous culture or knowledge was during the 1967 revision of the Berne Convention for the Protection of Literary and Artistic Works.⁷ Even though those discussions failed to give effective protection to folklore, they led to sensitization about the possible misappropriation of Indigenous knowledge and culture through the IP system. However, it took another three decades for the discussions to gain a formalized structure in the form of the WIPO IGC on IPRs and GRTK.

In 2000, the WIPO IGC was established as an intergovernmental body with representatives from WIPO Member States as participants.⁸ The WIPO IGC sessions were convened at headquarters in Geneva and usually lasted around five days. As negotiations progressed, it became evident that the views of the global South and North were diametrically opposite with regard to the protection of GRs, ATK, TK, and TCEs. While the developing countries were arguing for legally binding instruments that provide effective protection against misappropriation of source materials used for creating patented products, developed countries favored a flexible and nonbinding instrument that would complement the existing IP framework.

The discussions slowly progressed in the IGC for more than two decades before WIPO developed a draft instrument that could be placed before a diplomatic conference. The negotiations in the WIPO IGC significantly contrib-

uted to transforming the perception of GRs, ATK, TK, and TCEs, from being the common heritage of mankind to being a valuable asset critical for the creation of innovation and intellectual resources susceptible to protection by the IP system. The WIPO IGC process has also resulted in building up a robust international understanding of the issues. The negotiations in the area of GRs and ATK alone finally culminated into the “Basic Proposal” that was presented for final negotiation in the Diplomatic Conference.

II. WIPO GRTK Treaty

Significantly, the WIPO General Assembly in July 2022 resolved to hold a diplomatic conference to finalize an international legal instrument pertaining to IP, GRs, and ATK.⁹ The Diplomatic Conference, held at WIPO headquarters in Geneva from May 13-24, 2024, was an important next step after a WIPO IGC meeting in September 2023 to finalize a draft negotiating text. The Preparatory Committee approved the draft rules of procedure, administrative provisions, and final clauses for the instrument.

The final negotiating texts (Basic Proposal) owed their origins to the draft “Objectives and Principles” first published by the WIPO secretariat in 2005. The Basic Proposal is the result of negotiations that took place over two decades and thus reflects the view of different Member States. The latest draft of the text with no options, prepared by a former chair of IGC in April 2019 and commonly known as the “Chair’s text,”¹⁰ with minor modifications formed the Basic Proposal for the Diplomatic Conference.¹¹

Eventually, the Diplomatic Conference resulted in the adoption of the WIPO GRTK Treaty.¹² The treaty consists of 22 articles, of which the first nine constitute the main operative part of the instrument. The remaining articles deal with procedural and administrative matters.

In the preamble, the text highlights the desire to promote efficacy, transparency, and quality of the patent system in relation to GRs and ATK. The instrument recognizes that an international disclosure requirement related to GRs and ATK in patent applications contributes to legal certainty and consistency. The treaty’s objectives are limited to providing or promoting attribution to traditional sources in patent applications. Basically, it addresses the complaint that patents are granted to improvements made over TK without acknowledging the source. The treaty’s

(adopted by Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources, and Traditional Knowledge Associated With Genetic Resources, Geneva, May 13 to 24, 2024), https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_7.pdf.

6. WIPO GRTK Treaty, *supra* note 5.

7. WIPO, WIPO PUB. NO. 913(E), INTELLECTUAL PROPERTY AND TRADITIONAL CULTURAL EXPRESSIONS/FOLKLORE, https://www.wipo.int/edocs/pubdocs/en/tk/913/wipo_pub_913.pdf.

8. WIPO, *supra* note 4.

9. WIPO, *Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge: Geneva, May 13-24, 2024*, <https://www.wipo.int/diplomatic-conferences/en/genetic-resources/index.html> (last visited Aug. 7, 2024).

10. WIPO IGC, *Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources, and Traditional Knowledge Associated With Genetic Resources*, U.N. Doc. WIPO/GRTKF/IC/43/5 (May 3, 2022).

11. WIPO IGC, *Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources, and Traditional Knowledge Associated With Genetic Resources*, U.N. Doc. WIPO/GRTKF/IC/SS/GE/23/2 (June 30, 2023) (reviewed at Special Session Sept. 4-8, 2023); WIPO IGC, *Decisions*, U.N. Doc. WIPO/GRTKF/IC/SS/GE/23/4 (Sept. 8, 2023) (Special Session Sept. 4-8, 2023); Pedro Henrique D. Batista, *The WIPO IGC Chair’s Draft on IP and Genetic Resources—Reasons for Concern*, 19 J. INTEL. PROP. L. & PRAC. 328 (2024).

12. See generally WIPO GRTK Treaty, *supra* note 5.

limited purpose is to facilitate acknowledgement of sources when granting patent protection to GRs and TK associated with GRs.

Such attribution to ATK sources facilitates investment and inventions based on GR/ATK subject to satisfying limited mandatory obligations of disclosures involving GR/ATK. Unfortunately, the treaty does not envisage tangible benefits such as monetary returns to the country of origin of GRs and the holders of GR/ATK for having supplied the resource that creates private property. Beyond the limited purpose of ensuring attribution, the treaty has not fully addressed the demands of the traditional communities. The treaty's objective is limited to preventing misappropriation of existing TK by ensuring disclosure of GR/ATK prior-art materials in patent applications.

We, the authors, term such disclosure “attribution obligation,” as the treaty obligates patent applicants to include information on country of origin of the GR and the Indigenous/local community holding GR/ATK. The limited nature of the objective leaves an impression that the treaty is defensive in nature arguably because it does not mean to address larger issues that affect knowledge holders, such as effects of erroneous grant of patents embodying GRs and TK, and/or compensating knowledge holders. Nevertheless, the first step of proving attribution obligation by including information on country of origin of the GR and the Indigenous/local community holding GR/ATK is a step in the right direction.

In effect, arguably, the treaty will be beneficial in that the patent disclosures will benefit both providers and users. The text emphasizes the importance of patent offices having access to information on the sources of GRs and ATK, thus opening the door for such ATK or genetic information to be memorialized. This will greatly help the patent offices in preventing erroneous grants of patents for inventions that should otherwise rightfully be in the public domain, but will allow contracting Parties the flexibility to seek more details about the ATK based on which invention is developed.¹³

A. Treaty Obligation

Independently, the two main objectives of the treaty are to (1) enhance the efficacy, transparency, and quality of the patent system, and (2) prevent patents from being granted erroneously for inventions that are not new or inventive. Thus, the treaty covers the disclosure of GRs and ATK in patent applications to achieve these objectives. In doing so, the treaty arguably facilitates investment and inventions based on GR/ATK subject to satisfying limited mandatory obligations of disclosures involving GR/ATK. The attribution obligation is to include information on country of origin of the GR and the Indigenous/local community holding GR/ATK.

13. See *id.* art. 3.4. See also Wend Wendland, *Is an International Agreement on IP, Genetic Resources, and Associated Traditional Knowledge Finally in Sight?*, WIPO MAG. (Feb. 2023), https://www.wipo.int/wipo_magazine_digital/en/2023/article_0003.html.

Notably, the treaty obligations are triggered when a patent application is “based on” GR or ATK information.¹⁴ The term “based on” means that the GR or ATK must have served as the *necessary* basis for the claimed invention and that the claimed invention must *depend* on the specific properties of the GR and/or on the ATK.¹⁵ Thus, only inventions that come under this categorization—based on GRs or ATK—will be covered under the treaty attribution-and-disclosure obligation. The terms “genetic resources” and “genetic material” are given the same definitions as existing in the CBD.¹⁶ The combination of these definitions creates the impression that the treaty is applicable only in cases where physical material of GRs is used in the invention.

The treaty clearly dissociates from instances of contemporary practices in biotechnological research related to the use of chemical equivalents, synthetic alternatives, and digital sequence information. As such, the disclosure requirement is closely connected with the physical resource. Use of intangible forms of GRs is not covered, presumably because it may become a stretch to cover such situations, especially if it is not in the public domain or is memorialized in some form.

Member States are free to seek additional information through their statutes by requiring disclosure of the depository or data library to help trace the source by creating a linkage with the tangible material.

B. Mandatory Disclosure Requirement

The GRTK Treaty defines the source of GRs as “any source from which the applicant has obtained the GR, such as a research center, gene bank, Indigenous Peoples and local communities, the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other *ex situ* collection or depository of GR.”¹⁷ If the patent applicant is unaware of the country of origin of the GR, the obligation is to disclose the “source of the GR.” Similarly, if the applicant is not aware of the community to which the TK belonged, the obligation under Article 3.2(b) is to disclose the “source of ATK.”¹⁸

According to the treaty, the “source of ATK” “means any source from which the applicant has obtained the ATK, such as scientific literature, publicly accessible databases, patent applications and patent publications information.”¹⁹ Even this arguably limited requirement is further diluted by Article 3.3, which gives an option to the patent applicant to file a declaration to the effect that the above information is not known to the applicant “affirming that the

14. See WIPO GRTK Treaty, *supra* note 5, art. 3.

15. *Id.* art. 2.

16. See CBD art. 2, June 5, 1992, 1760 U.N.T.S. 79, 31 I.L.M. 818.

17. For discussions on different views expressed by countries, see generally Note, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/356 (June 24, 2002).

18. See WIPO GRTK Treaty, *supra* note 5, art. 3.

19. *Id.* art. 2.

content of the declaration is true and correct to the best knowledge of the applicant.”²⁰

Considering that the GR/ATK pool was created at the insistence of countries that were rich in such resources, it is understandable that some inventors may be able to create inventions from what is deposited in the international forums such as the ITPGRFA. Similarly, the cost of the exercise to locate the source is likely to discourage private inventors from investing time and energy on it. In order to prevent patent applicants from using the affidavit to withhold knowledge of the source of the information, and/or to allow applicants to use the opportunity to rectify the failure or correct any disclosures that are erroneous or incorrect, Member States may have to provide for appropriate measures in their national patent statutes.

The disclosure requirement under the treaty is mandatory, which is appreciable. Thus, patent applications in which the claimed invention is based on GRs or ATK are mandated to provide additional disclosures. That is, contracting Parties shall require such patent applications to disclose the country of origin of the GR, or if the subject matter is TK, the Indigenous peoples or local community that provided the TK. But if the origin is not known to the applicant, then the source of the GR or TK, as the case may be, shall be given.²¹ Where the knowledge of the origin or the source of the material is either unavailable generally or is unknown, the patent applicant shall make a declaration to that effect.²²

National patent offices shall provide guidance to applicants to meet the mandated disclosure requirement and provide opportunities for patent applicants to rectify a failure to include minimum information or correct any erroneous or incorrect disclosures.²³ The text also provides that the contracting Parties shall not place an obligation on patent offices to verify the authenticity of the disclosure, presumably because of the cost and time involved.²⁴ Thus, the only positive obligation the treaty creates on the patent applicants is to disclose the origin/source of the GR and/or ATK on which the invention is based. However, the patent applicant can easily circumvent this obligation by declaring that the source is unknown.

In instances where the invention is clearly “based on” GR/ATK but the applicant does not provide the information, the treaty does not provide for opportunities for the patent examiner to raise the issue of reliance over a GR/ATK. Nevertheless, countries will be able to institute such a mechanism through their statutes by creating situations where a patent examiner may be able to raise a reasonable question about the disclosure. Similarly, countries can also add some form of incentives or sanctions to prevent applicants from denying their reliance over GRs or ATK by establishing a process to deal with such situations.

20. *Id.* art. 3.3.

21. *Id.* arts. 3.1(b), 3.2(b).

22. *Id.* art. 3.3.

23. *Id.* art. 3.4.

24. *See id.* art. 3.5.

C. Sanctions and Remedies

Tied closely to the above is the treaty requirement that each contracting Party put in place appropriate, effective, and proportionate legal, administrative, or policy measures to address an applicant’s failure to satisfy the disclosure requirement. The contracting Party shall allow the applicant to rectify a failure to include the minimum information before implementing sanctions or directing remedies. The instrument makes it clear that no contracting Party shall revoke or render unenforceable a patent solely on the basis of an applicant’s failure to meet the disclosure requirement.²⁵ The only exception is if there has been fraudulent intent in the failure to disclose and exclusion from the opportunity to rectify; then the contracting Party may provide post-grant sanctions or remedies.²⁶ Sanctions provided under the instrument are weak. Thus, the treaty does not prevent Members from including more significant sanctions to enforce the obligations.

Member countries also have flexibility under Article 5.2(bis) of the treaty to determine “fraudulent contact or intent” under their national laws. While Member States have the flexibilities to weave in effective incentives to promote disclosure or sanctions to deter failure to disclose due to “fraudulent intent,” it is unclear how many States will create elaborate procedures to determine fraudulent intention considering the operational barriers of implementing them. Further, the administrative time and cost involved in traversing the burden of establishing fraud alone renders this inefficient. The evidentiary burdens imposed on proving both the adequacy of disclosure as well as intent to determine fraud are significant.

Perhaps, recommendations for imposing on the patent applicant a burden to establish lack of “fraudulent contact or intent” is a workable suggestion, although that too will leave every application susceptible to the long-winded examination process of a system that is already stymied by delays. Member countries may also consider whether the extent of biodiversity in their country warrants a provision to revoke patents in the event an opposer is able to establish fraud or inadequate disclosure.

Another option may include levying a fine that deters nondisclosure, insufficient disclosure, or fraudulent disclosure. The collected fines should be used for the benefit of the community. Although this treaty does not have a provision for sanctioning or for benefit-sharing, including compensating the TK holders, the treaty does not prevent Member States from instituting such provisions by tying in the Nagoya Protocol and other CBD provisions.

In any case, the components of what amounts to fraudulent withholding or intent cannot be expected to be uniform in all the Member countries. What may be a fraudulent contact or intent in one country may not be the same in another country. The result is that some countries may allow a patent based on the same information while

25. *Id.* art. 5.3.

26. *Id.* art. 5.4.

others may categorize it as misappropriation of GR/ATK. Obviously, sanctions, if any, also will differ in Member States. Naturally, revocation or invalidation of a patent for nondisclosure of knowledge would be an effective mechanism to incentivize adequate disclosures, which the treaty does not seem to prevent nations from imposing.

In all, the highlight of Article 5 is that the treaty provides flexibility to Member States to decide the nature of sanctions or remedies for noncompliance. Clearly, countries in need of access to GR/ATK for research and development have the freedom to provide very minimal non-deterrent provisions for failure to disclose.

Perhaps, the recommendation below to create a pre-grant opposition mechanism would help alleviate some of the issues by enabling the opposer to establish withholding of information by applicants/inventors.

D. Information Systems

Article 6 of the treaty provides that contracting Parties may establish information systems such as databases of GRs and ATK. Where applicable, Indigenous communities, local communities, and other stakeholders shall be consulted.²⁷ The contracting Parties should, with appropriate safeguards, make such information systems accessible to patent offices for the purposes of searching and examining patent applications.

Such access to the information systems may be subject to authorization by the contracting Parties establishing the information systems. This should be done with appropriate safeguards and in consultation with Indigenous peoples, local communities, and other stakeholders. The treaty also provides for the establishment of technical working groups by the Assembly to address any matters relating to the information systems, such as accessibility to patent offices with appropriate safeguards.²⁸ Interestingly, the treaty obligation for the biodiversity-rich countries to create databases on their GR/ATK will hopefully enlarge the scope of the prior-art searches globally.

III. Suggestions and Recommendations

While the treaty only creates a limited disclosure requirement, it is a significant leap toward creating an effective TRIPS-CBD link. Thus, the developing world should consider this an opportunity to reform its national law and create effective procedures to prevent misattribution/misappropriation of GRs and ATK. In this context, it is important to identify the steps that the developing world can adopt within and beyond (GRTK+) the treaty's framework.

A. Mandatory Disclosure Requirement in National Patent Law

The treaty mandates disclosure requirements within the patent law regarding the origin/source of the GR and ATK. However, domestic patent law may seek additional information regarding GR/ATK and provide the procedures for disclosure. In India, for instance, the patent law requires disclosure regarding the origin/source of GRs to be made in the specification.²⁹ Even though the patent office insists on this requirement during the examination, this provision has been grossly ineffective in preventing misappropriation, as this mode of disclosure does not facilitate tracking or monitoring.

Thus, it is important for developing countries to seek additional information relating to GR/ATK for disclosures such as the nature of TK, complete details of the TK used in the invention, specific properties of the TK used in the invention as understood by the holders of the knowledge system, source of TK, details of the holders of TK, and available experts in the relevant field, and to establish a procedure for disclosure in national law. This disclosure should be tailored to facilitate tracking of the GR/ATK, where possible. Even where the GR/ATK are obtained from databases, the treaty has flexibilities such that each country may determine what type of information is required to fulfill the minimum requirements, keeping in mind the critical need for the information to help identify the ATK and the provider.

Some Member States may have undocumented GRs or ATK. The burden is on the country to ensure that these are fully documented, whether through patent application disclosures or other means to prevent creation of private property from either publicly known or known-only-within-community knowledge. Individual nations may also institute benefit-sharing mechanisms as needed.

Significantly, the burdens of determining the extent of disclosure and ensuring disclosure are both on the Member State. With respect to the extent of disclosure, the treaty allows Member States to determine how much disclosure is needed. With reference to ensuring disclosure, each Member State can and should sensitize Indigenous communities and facilitate the creation of written documentation in order to create a strong database of prior arts.

B. Developing Tools to Search, Identify, and Verify Disclosures

The only positive obligation that the treaty creates for the patent applicant is requiring attribution by disclosing the origin/source of the GR/ATK on which the claimed invention is based. The national governments must develop information technology-based tools that can be used to search, identify, and verify disclosures effectively.

27. *Id.* art. 6.1.

28. Assembly established under Article 10 of the WIPO GRTK Treaty.

29. The Patents Act, 1970, §10(4)(ii)(D) (India) (Act No. 39 of 1970, amended up to Act No. 15 of 2005).

For instance, the Office of the Controller General of Patents, Designs, and Trade Marks (Indian Patent Office) maintains a searchable database that lists applications based on TK.³⁰ Such active databases prepared in consultation with the knowledge holders on publicly available information can memorialize and enlarge the public domain. Initiatives from the developing world to create platforms that create such databases would eventually help acknowledge and provide attribution for GR/ATK and may become an important tool for the future to preserve the interests of the knowledge holders.

C. Pre-Grant Opposition Process

In order to improve efficiencies and promote full disclosure, the authors suggest that Member States should establish a pre-grant opposition opportunity to achieve the objectives of the WIPO GRTK Treaty.

Generally, to get patent protection, an invention should be (1) new, useful, and nonobvious when compared with the prior art, and (2) comport with statutory disclosure requirements. Typically, published literature in the field of relevant art and prior patents serve as a major source of prior art. While the inventor is required to disclose the prior art, the examiner has a burden to conduct a thorough search of all prior arts to determine patentability.

In order to prevent patent office errors due to various factors such as inadequate information, lack of expertise in the field of the invention, prior use of the invention, and so on, recommendations for WIPO GRTK Treaty implementation in Member States, whether in the form of a law, protocol, or rules, should encourage Member nations to create a pre-grant opposition procedure. An effective pre-grant opposition process would enable the interested parties to oppose patent applications with inadequate disclosure, incorrect disclosure, or nondisclosure.

Significantly, inventions based on GR/ATK are the outcome of the interaction of two different knowledge systems. The application of new techniques of biotechnology to GR/ATK results in the development of biotechnology products. The two knowledge systems differ substantially in terms of the science, terminology, logic, mode of expression, language, and the like. Modern biotechnology is the outcome of teachings of science and technology developed post-Industrial Revolution and, hence, is prevalent substantially in written form. GR/ATK's knowledge differs not just in the use of terminology, logic, and mode of expression, but a substantial portion is either unrecorded or passed on generationally through word of mouth. Even when documented, some details typically normal for contemporary knowledge/science regarding usage and properties remain absent.

Thus, persons trained in GR/ATK are best positioned to appreciate the nature and content of the knowledge

involved. Hence, where an invention is based on GR/ATK, whether undocumented or documented in local language or based on oral traditions, the treaty or recommendations therefore should involve the knowledge holders. After all, patent prosecutions involve the inventor on the assumption that they are the best positioned to disclose the information and the inventive process.³¹ Here too, the opportunity for pre-grant opposition can help interested opposers to appropriately clarify and contextualize the disclosures and prevent misattribution.

The history of WIPO GRTK Treaty negotiations suggests an initial demand by the countries rich with GR/ATK to include a composite disclosure such as the country of origin of GRs, the details of the holder of GR/ATK, the details of the existing TK used in the invention, and the evidence of prior informed consent and benefit-sharing from the country of origin, as mandated in the CBD.³² This was opposed on the ground that it adds additional prosecution burdens on the patent office, affecting cost and efficiency of the system.

The concern was that such a disclosure requirement will disincentivize investment and innovation in GR/ATK.³³ Nevertheless, the mandatory disclosure requirement under Article 3 of the treaty is confined to disclosing the country of origin of the GR as well as the Indigenous tribe or local community from which TK has been obtained.³⁴ Pre-grant opposition can result in enriching the information about the prior art by providing more details of the TK used in the invention.

Establishing a pre-grant opposition will ensure an opportunity for persons interested in the relevant field to inform the patent office of existing prior art and aid in the evaluation of patentability. Some countries, such as India, already have elaborate procedures for entertaining pre-grant oppositions, while others, such as the United States,

31. For a detailed analysis, see Gopalakrishnan, *supra* note 2.

32. See CBD, *supra* note 16. For representations made by India and Asian and African countries, see also Communication From India, *Proposals on Intellectual Property Rights Issues*, WTO Doc. IP/C/W/195 (July 12, 2000); Note, *supra* note 17; Communication From UNCTAD, *Seminar on Systems for the Protection and Commercialization of Traditional Knowledge*, WTO Doc. IP/C/W/350 (June 26, 2002); Communication From the European Communities and Their Member States, *Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/383 (Oct. 17, 2002); see generally WTO, *Review of TRIPS Article 27.3(b); Relationship Between the TRIPS Agreement and the Convention on Biological Diversity; Protection of Traditional Knowledge and Folklore*, https://www.wto.org/english/tratop_e/trips_e/ta_docsec4_e.htm (last visited Aug. 7, 2024); see also *Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, WTO Doc. WT/CET/W/223 (Feb. 14, 2003), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q/W/CTE/W/223.pdf&Open=True>.

33. For details, see Communication From the United States, *Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement*, WTO Doc. IP/C/W/257 (June 13, 2001); Communication From the United States, *Technology Transfer Practices of the US National Cancer Institute's Departmental Therapeutics Programme*, WTO Doc. IP/C/W/341 (Mar. 25, 2002); Communication From the United States, *Access to Genetic Resources Regime of the U.S. National Parks*, WTO Doc. IP/C/W/393 (Jan. 28, 2003).

34. See WIPO GRTK Treaty, *supra* note 5.

30. See Indian Patent Office, *Dynamic Patent Utilities: Dynamic Status of Patent Applications as Per Field of Invention*, <https://iprsearch.ipindia.gov.in/DynamicUtility/DynamicStatus/Index> (last visited Aug. 7, 2024).

allow any third party to submit information that has a bearing on patentability of a claimed invention.³⁵ Similarly, the submission of third-party observation in the European Patent Office (EPO),³⁶ a protest petition in Canada,³⁷ and third-party observation in the WIPO Patent Cooperation Treaty (PCT)³⁸ are examples of systems that allow the submission of information that will aid the patent office in the substantive examination.

Member States can expand the scope of the information disclosures to include TK information, including its components, as part of pre-grant procedures. This will hugely improve and aid in achieving the treaty goals as well as in examining for novelty and determining obviousness. Such pre-grant opposition opportunities can be a powerful procedural safeguard that countries can institute to issue quality patents and enhance search efficacy and transparency.

D. *Link With the CBD*

Many countries that could accede to the treaty may also be signatories of the CBD-Nagoya Protocol framework.³⁹ The Nagoya Protocol requires its Parties to institute frameworks to monitor the utilization of GR/ATK.⁴⁰ The GRTK Treaty rightfully insists that contracting Parties shall not place an obligation on patent offices to verify the authenticity of the disclosure, considering that the main charge of the patent office is to examine the presence of innovation in the application materials. Thus, patent examiners cannot be expected, nor are they trained, to indulge in examining the authenticity of prior arts.

This, in effect, means that patent offices will collect the disclosures of origin/source and make them available under this treaty, which fully comports with the stated objectives of the treaty. It results in creating a rich database of GR/ATK prior art for the examiner. Creating such databases of TK and GRs has several benefits such as creating a strong database of prior arts, which will be critical to prevent inadvertent privatization of what would otherwise be in the public domain. Similarly, it can create an arm's-length distance between the scientist and the TK holder without compromising access to science but at the same time minimizing the opportunities to misuse knowledge gained from close associations. Member countries can create a benefit-sharing mechanism more fully described under the Nagoya

Protocol to provide for compensation where GR/ATK have been used to create high-value private property.

This creates an opportunity for developing countries to create frameworks to verify authenticity of GR/ATK under the Nagoya Protocol. In any case, there is no need for two separate international instruments to address the same issue of verifying the authenticity of the material. Perhaps, in order to facilitate operations, patent applicants may be mandated to submit disclosure statements to a national body that would issue a checkpoint communique through the Access and Benefit-Sharing Clearing-House mechanism portal of the CBD secretariat. This could significantly enable verification of authenticity.⁴¹

IV. Role of Biodiversity-Rich Countries

Biodiversity-rich nations can be proactive in the adoption of GRTK Treaty measures, which can also include sanctions for noncompliance with disclosure requirements. A collective stance by the developing world in support of GRTK Treaty measures would help in achieving better compliance. Countries rich in biodiversity can institute GRTK+ measures to ensure that there is an effective mechanism to disclose and to control the extent of disclosures.

For biodiversity-rich countries, the Indian experiment to protect biodiversity as well as GR/ATK issues would serve as a great example. India has long been engaged in a pursuit to protect its TK. India's quest to protect TK is primarily motivated by the desire to stop others from misappropriating. India deems the patenting of inventions that are based on GRs or ATK obtained from India as misappropriation. The allegation is that often, Indigenous knowledge is commercialized in a manner that results in no benefit to the communities that have preserved and developed it over generations.

Starting with the Indian initiatives in the 1990s to oppose the grants of patents on turmeric and neem, India has adopted many measures to address the issues of misappropriation. This was followed by legal changes, including making it mandatory to disclose the source and geographical origin of the GR/ATK in the complete specification.⁴² Nondisclosure or wrongful disclosure is grounds for pre-grant and post-grant oppositions.⁴³ Disclosure requirements also improve the prior-art materials that will ultimately prevent the grant of patents embodying undisclosed traditional materials in India.

The application can also be opposed and revoked on the ground that the claimed invention is "anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."⁴⁴ This particular provision in the Indian statute

35. Pre-issuance Submissions and Protests by Third Parties, 37 C.F.R. §§1.290, 1.291 (2013).

36. European Patent Convention art. 115, Oct. 5, 1973 (providing that "any third party may, in accordance with the Implementing Regulations, present observations concerning the patentability of the invention" to the EPO).

37. Patent Act, R.S.C. 1985, c P-4, §34.1 (Can.) (providing for the filing of "Protests" and "prior art" prior to the grant of a patent).

38. See Third Party Observation System, Administrative Instructions Under the PCT §801, <https://www.wipo.int/pct/en/texts/ai/s801.html> (last visited Aug. 7, 2024).

39. 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, Oct. 29, 2010, 3008 U.N.T.S. 3, <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

40. *Id.* art. 17.

41. Article 14 of the Nagoya Protocol establishes an Access and Benefit-Sharing Clearing-House portal. *Id.*

42. The Patents Act, 1970, §10(4)(ii)(D) (India).

43. Incorrect or wrongful disclosure is a ground for pre-grant opposition under §25(1)(j) or post-grant opposition under §25(2)(j) of the Patents Act, 1970. *Id.*

44. *Id.* §§25(1)(k), 64(p).

enables countries to ensure documentation of oral materials, and thus should be emulated by biodiversity-rich countries that also have undocumented GR/ATK. Similarly, Form 1 in the Indian Patent Rules mandates the applicant to declare regarding the permission required from the competent authority in respect of the biological material used in the invention.⁴⁵ These requirements are also part of the Manual of Patent Office Practice and Procedure, followed by the Indian Patent Office.⁴⁶

The *Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material* of December 18, 2012, deals with prosecuting patent applications embodying TK and related materials.⁴⁷ Similarly, the *Guidelines for Examination of Biotechnology Applications for Patent* of March 25, 2013, issued by the Indian Patent Office, also emphasizes the disclosure requirement relating to prosecution of the respective applications.⁴⁸ This has significantly improved India's patent system in promoting disclosure requirements and preventing the grant of patents embodying GR/ATK.

Countries that are rich in biodiversity may include provisions that facilitate more detailed disclosures and may require additional burdens on the patent holder to prevent withholding information.

V. Conclusion

The WIPO GRTK Treaty creates obligations about disclosure of origin and falls short of providing any positive protection to GR/ATK. Countries that are rich in biodiversity should establish standards and disclosure requirements that go above the minimum requirements of the treaty. Further, the adoption of this treaty need not deter the developing world from continuing its efforts to develop a *sui generis* regime for the protection of GR/ATK.

The adoption of the GRTK Treaty thus presents a unique moment for countries such as India to be a forerunner by establishing a strong stance on disclosure requirements. India would be a great example to emulate for countries interested in creating such standards.

45. *Id.* Form 1.

46. INDIAN PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, VERSION 3.0 (2019), https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf.

47. *See generally* INDIAN PATENT OFFICE, GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL (2012), https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf.

48. *See generally* INDIAN PATENT OFFICE, GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT (2013), https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf.