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

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ABSTRACT

A new WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge was adopted on 24 May 2024. The treaty creates an international obligation for patent applicants to disclose the source or origin of genetic resources (GRs) and associated traditional knowledge (TK) in patent applications. This development marks a significant step towards mitigating the misappropriation of GRs and TK, particularly benefiting developing countries that have long advocated for such a framework. While the treaty establishes minimum standards for disclosure and sanctions, it permits contracting parties considerable flexibility in implementation and opens avenues for future expansion of its scope to address emerging technologies and derivative products.

KEYWORDS: *WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, World Intellectual Property Organization (WIPO), Diplomatic Conference, Genetic Resources (GRs), Traditional Knowledge (TK), Disclosure, Patents, Information Systems, Access and Benefit-Sharing (ABS)*

KEY MESSAGES

- "The treaty creates an international obligation for patent applicants to disclose the source or origin of genetic resources (GRs) and associated traditional knowledge (TK) in patent applications. This development marks a significant step towards mitigating the misappropriation of GRs and TK, particularly benefiting developing countries that have long advocated for such a framework."
- "Compliance with the new treaty obligations and monitoring of patent applications would allow for the implementation of benefit sharing obligations as contained in biodiversity national regimes and international law".
- "Despite its narrower scope and limitations compared to some national laws, the treaty sets minimum disclosure standards and allows for broader national regulations. Its effectiveness will hinge on its rapid entry into force and a commitment to expand the scope of its coverage".

Un nouveau traité de l'OMPI sur la propriété intellectuelle relative aux ressources génétiques et aux savoirs traditionnels associés a été adopté le 24 mai 2024. Le traité crée une obligation internationale pour les demandeurs de brevets de divulguer la source ou l'origine des ressources génétiques (GRs) et des savoirs traditionnels associés (TK) dans les demandes de brevets. Cette évolution marque une étape importante dans l'atténuation de l'appropriation illicite des ressources génétiques et des savoirs traditionnels, en particulier au profit des pays en développement qui plaident depuis longtemps pour la mise en place d'un tel cadre. Bien que le traité établisse des normes minimales en matière de divulgation et de sanctions, il laisse aux parties contractantes une grande marge de manœuvre dans sa mise en œuvre et ouvre la voie à une extension future de son champ d'application afin de prendre en compte les technologies émergentes et les produits dérivés.

MOTS-CLÉS: *Traité de l'OMPI sur la propriété intellectuelle relative aux ressources génétiques et aux savoirs traditionnels associés, Organisation Mondiale de la Propriété Intellectuelle (OMPI), Conférence diplomatique, Ressources génétiques (GRs), Savoirs traditionnels (TK), Divulgation, Brevets, Systèmes d'information, Accès et partage des bénéfices*

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El 24 de mayo de 2024 se adoptó un nuevo Tratado de la OMPI sobre la Propiedad Intelectual, los Recursos Genéticos y los Conocimientos Tradicionales Asociados. El tratado crea una obligación internacional para los solicitantes de patentes de divulgar la fuente o el origen de los recursos genéticos (RG) y los conocimientos tradicionales asociados (CC.TT.) en las solicitudes de patentes. Este avance supone un paso importante para mitigar la apropiación indebida de los recursos genéticos y los conocimientos tradicionales, y beneficia especialmente a los países en desarrollo, que llevan mucho tiempo abogando por un marco de este tipo. Aunque el tratado establece normas mínimas de divulgación y sanciones, permite a las partes contratantes una considerable flexibilidad en su aplicación y abre vías para una futura ampliación de su ámbito de aplicación a fin de abordar las tecnologías emergentes y los productos derivados.

PALABRAS CLAVES: *Tratado de la OMPI sobre la Propiedad Intelectual, los Recursos Genéticos y los Conocimientos Tradicionales Asociados, Organización Mundial de la Propiedad Intelectual (OMPI), Conferencia Diplomática, Recursos genéticos (RG), Conocimientos tradicionales (CC.TT.), Divulgación, Patentes, Sistemas de información, Acceso y reparto de beneficios*

On 24 May 2024, the Member States of the World Intellectual Property Organization (WIPO) adopted a historic international treaty on Intellectual Property, Genetic Resources and Traditional Knowledge in a Diplomatic Conference that negotiated the final text of the treaty.

The adoption of this treaty marks a partial resolution of a quest for nearly a quarter of a century by developing countries in WIPO to establish a multilateral legal framework that may contribute to identify cases of misappropriation of genetic resources and associated traditional knowledge from those countries.

In 1999 developing countries requested in the WIPO Standing Committee on the Law of Patents (SCP) to start discussions on intellectual property (IP), genetic resources (GRs) and traditional knowledge (TK). In 2000 the WIPO General Assembly established an intergovernmental committee (IGC) as a time-limited body to discuss IP issues that arise in the context of GRs, TK and expressions of folklore (TCEs). The original mandate of the IGC essentially rendered it a discussion forum, but in 2009 the WIPO General Assembly renewed the mandate of the IGC to undertake text-based negotiations. The mandate has been renewed biennially by the WIPO General Assembly since then. Under this mandate the IGC negotiations focused on three separate texts on GRs, TK and TCEs. Of these, the GRs negotiations have been concluded through the adoption of a treaty in the recently held WIPO Diplomatic Conference.

From the outset of the Diplomatic Conference, the scope of the treaty as laid out in the Basic Proposal submitted by the Secretariat reflecting some of the texts considered by the IGC, was narrow.[1] It sought to introduce an international obligation of mandatory disclosure of source or origin of GRs and associated TK in patent applications based on GRs and associated TK, and included provisions to improve the information available to patent offices in their prior art search when presented with patent applications for inventions that involve GRs and associated TK.

For the international patent system, the international disclosure mechanism on GRs and associated TK is expected to increase transparency, an important legal principle for the functioning of the patent system, while not unduly burdening patent offices. Such disclosure can be valuable in assisting the appropriate national authorities in supporting obligations that Parties have under international and national access and benefit sharing (ABS) regulations to ensure that users of GRs and associated TK comply with the established requirements for access to GRs, including prior informed consent and benefit sharing under mutually agreed terms.[2]

Many countries currently provide for national disclosure requirements concerning GRs and associated TK in patent applications. In this context, an international disclosure requirement established under a WIPO treaty can establish a baseline that will require patent offices of all contracting parties to the treaty to implement the disclosure requirement.[3]

However, leading into the Diplomatic Conference it was not clear whether the proposed treaty established minimum or maximum legal standards regarding the scope of the disclosure requirement and sanctions for non-compliance with the disclosure requirement. It was also unclear whether digital sequence information (DSI) would be included within the scope of the disclosure requirement, and how the disclosures made can be used to monitor patent claims that are based on GRs or associated TK in multiple jurisdictions. While article 9 of the treaty allows contracting parties to provide for additional obligations (e.g., for the patent applicant to inform about compliance with ABS regulations), it will be a matter of interpretation whether the Treaty obligations extend to DSI. In any case, the absence of specific reference to DSI (despite the discussions in the context of the Convention on Biological Diversity and the recent treaty on Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction "creates loopholes of escape as national laws will not be consistent on mandatory disclosure requirement".[4]

The following are some of the major changes in the final act from the basic proposal:

Definition of the trigger of disclosure requirement

Intense negotiations took place on the definition of the trigger of the disclosure requirement in the list of terms under article 2 of the basic proposal. The basic proposal in article 3 allowed the

1 Viviana Munoz Tellez, "The WIPO Diplomatic Conference for a Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge", Policy Brief No.129, 7 May 2024, South Centre, Geneva, available from https://www.southcentre.int/wp-content/uploads/2024/05/PB129_The-WIPO-Diplomatic-Conference-for-a-Treaty-on-Intellectual-Property-Genetic-Resources-and-Associated-Traditional-Knowledge_EN.pdf.

2 Ibid.

3 Ibid.

4 TWN, "WIPO: US-led developed countries pushed to control genetic resources and traditional knowledge treaty", 28 May 2024, available at https://twn.my/title2/intellectual_property/info.service/2024/ip240506.htm.

disclosure requirement to be triggered if the claimed invention in the patent application was "materially/directly based on" GRs and/or associated TK.

Article 2 defined "materially/directly based on" to mean that the GR and/or associated TK must have been necessary or material to the development of the claimed invention and that the claimed invention must depend on the specific properties of the GR/associated TK. In the final act the references to materiality and directness of the GRs and associated TK to the claimed invention was removed. Thus, the disclosure requirement under article 3 –the "main victory" for the *demandeurs* of the treaty–[5] will be triggered if the patent claim is "based on GRs". However, as per the agreed definition of "based on" in article 2, the patent claim will be deemed to be based on GRs/associated TK if it is necessary to the development of the claimed invention, and cumulatively, the claimed invention depends on the specific properties of the GRs/associated TK. This definition is narrower than the triggers of disclosure found under some national laws that are broadly based on "use" of GRs in an invention without any need for establishing the "necessity" of the GR used for the claimed invention but rather whether the GR or associated TK is mentioned in the "patent specification". While patent claims define the legal scope of protection, the patent specification describes the invention and provides support for the claims. The treaty wording "claimed invention" leaves some ambiguity as to whether the GRs/associated TK should be specifically mentioned in the patent claims or whether it would be sufficient to trigger the obligation if the GRs/associated TK are described in the patent specification. The former interpretation may allow the drafting of claims in a manner that by-pass compliance with the disclosure obligation and would be inconsistent with the treaty objectives as spelled out in article 1.[6]

In implementing the treaty, patent offices should mandate that the disclosure of the origin or source need to be made in the patent application itself, including the title and/or abstract, as the application will normally be published after 18 months of the filing date. If no reference is made in the title or abstract, or it is done in a separate document, it will be extremely difficult to monitor any disclosures.

Moreover, patent claims on inventions made using DSI of GRs are not specifically covered in the scope of the disclosure requirement. A significant portion of contemporary research based on GRs relies on sequences that are digitally uploaded through open databases, and numerous commercial products are developed from such DSI. Thus, for instance, a patent claiming a nucleic acid molecule comprised of a nucleic acid sequence derived from a specific sequence number could be deemed outside the scope of the disclosure requirement. However, nothing would prevent contracting parties from applying such requirements to DSI. The same applies, as mentioned below, to derivatives which are often the most valuable components in inventions based on GRs/associated TK.

A controversial issue during the negotiations was the right of patent applicants to amend an application before implementing sanctions or directing remedies. This right was finally recognized in the treaty unless "there has been fraudulent conduct or intent as prescribed by national law" (article 5.2(bis)). As noted by Flynn, "This suggests that a government who finds a failure to adhere to disclosure of GR and TK would have to allow for the missing information to be provided before invalidating or otherwise sanctioning the patent holder in any post-grant review. This is a key protection for patent holders in enforcement litigation where normally a defendant can respond to an enforcement action by proving that the patent was invalid because of a lack of adequate disclosures, for example of relevant prior art."[7] It is unclear, however, whether "a finding (but perhaps not appeal) of fraud must occur at some level of government before the refusal of a rectification opportunity".[8]

Deletion of exceptions to the disclosure requirement

An important outcome in the final act of the Diplomatic Conference was the deletion of article 4 on exceptions to the disclosure requirement as contained in the basic proposal. In fact, there was no justification for such an exception as the treaty did not refer to the grant of any rights.

Sanctions and remedies

A major focus of the negotiations during the Diplomatic Conference was on the provision on sanctions and remedies. Developed countries sought to reduce the policy space available under the treaty to determine sanctions and remedies and establish a ceiling in this regard. Though article 5.1 of the treaty requires contracting parties to put in place administrative, legal and/or policy measures to address failure by a patent applicant to provide the disclosure required under article 3, article 5.3 read with article 5.4 states that contracting parties cannot revoke, invalidate or render unenforceable the patent rights conferred on the sole basis of a failure to disclose the required information pursuant to article 3, unless there is fraudulent intent. However, this would not prevent a contracting party to provide for patent revocation if, for instance, the patent applicant fails to prove compliance with ABS regulations, which ultimately is the purpose of implementing an international disclosure obligation.

Moreover, article 5.3 seems to define a larger class of cases where revocation or invalidation may be a remedy as long as it is not a sanction "solely" for a failure to disclose. For example, what if in addition to the failure to disclose the applicant also did not rectify the failure within a reasonable time? That might be more than "solely" failing to disclose, even though it might be

5 Sean Flynn, WIPO TREATY ON GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE HARMONIZES DISCLOSURE AND REMEDIES, May 27, 2024, available at https://infojustice.org/archives/45782.
6 It has also been noted that given the general patent law disclosure requirements, "the fear of clever drafting bypassing the disclosure trigger may be unwarranted". See Sreenath Namboodiri, Countries Agree on Vital Disclosure Requirements on Genetic Resources and Traditional Knowledge at WIPO : A Win for Greater Balance in IP Politics, Geneva Health Files, June 3, 2024.
7 Ibid.
8 Ibid.

for reasons (failure of diligence, etc.) less than fraudulent intent.[9]

In terms of article 3.5 contracting parties cannot obligate patent offices to verify the authenticity of the disclosure made by applicants. Nevertheless, as mentioned by the South Centre in its statement at the conclusion of the Diplomatic Conference, [10] the treaty per se does not prevent patent offices from conducting such a verification.

Information systems

Under article 6 of the treaty, contracting Parties are allowed but not obligated to establish information systems such as databases of GRs and associated TK, and are encouraged to make these accessible to patent offices for purposes of search and examination of patent applications, with appropriate safeguards. Therefore, contracting parties can establish information systems such as the Traditional Knowledge Digital Library (TKDL) of India that provides patent offices with access to digitized and translated prior art documents relating to traditional knowledge, based on an access agreement with the patent office concerned, to safeguard against patenting of the information in the database by third parties. The Assembly of the contracting parties to the treaty may establish one or more technical working groups to discuss matters relating to such information systems.

An important difference in the final act from the Basic Proposal in respect of this provision is that references to a list of specific matters to be discussed under a technical working group were omitted in the final act. The issues proposed for discussion in relation to information systems included interoperability standards and structures of the content of information systems, guidelines and modalities of sharing information, guidelines on safeguards, and the possible establishment of an online portal hosted by the WIPO Secretariat through which offices would be able to directly access and retrieve data. However, these were not agreed upon in the final act.

Another element missing in the final act of the treaty in respect of information systems is a mechanism administered by the WIPO secretariat to receive and store communications from patent offices on patent applications containing claims on genetic resources or associated traditional knowledge. In its opening statement at the Diplomatic Conference, the South Centre[11] had stated that without a mechanism of this type, it will be almost impossible for governments and communities to monitor such claims in multiple jurisdictions.

Relationship with other international agreements

Article 7 of the treaty states that it will be implemented in a mutually supportive manner with other international agreements relevant to the treaty. This provision is accompanied by two agreed statements. Agreed statements are used in WIPO treaties to reflect an understanding between the parties regarding the text of a provision in a treaty.

The first agreed statement makes a request by the contracting parties to the Patent Cooperation Union to consider the need for amendments to the Patent Cooperation Treaty (PCT) Regulations and/or Administrative Instructions with a view towards providing an opportunity for applicants who file an international application under the PCT designating a PCT contracting State which, under its applicable national law, requires the disclosure of GRs and associated TK, to comply with any formality requirements related to such disclosure requirement either upon filing of the international application, with effect for all such contracting States, or subsequently, upon entry into the national phase before an office of any such contracting State.

The second agreed statement lays down that "Nothing in this Treaty shall derogate from or modify any other international agreement." This, in effect, implies that the treaty's provisions cannot be interpreted as a subsequent treaty that modifies obligations between parties under existing international agreements relating to intellectual property (IP) such as the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement). Therefore, the adoption of this treaty will not in itself imply that the mandatory disclosure requirement under this treaty will constitute an obligation between the parties to the TRIPS Agreement, unless a specific amendment of this Agreement in this regard is adopted. It is worth recalling that a proposal for amendment of the TRIPS agreement to include a mandatory disclosure obligation under article 29 bis of TRIPS has been on the agenda of the TRIPS Council and the Trade Negotiations Committee of the World Trade Organization (WTO) for several years.[12]

Review

Article 8 of the treaty states that the contracting parties commit to a review of its contents addressing issues such as extension of the disclosure requirement to other areas of IP and derivatives and addressing other issues arising from new and emerging technologies that are relevant to the application of the treaty. This review is to be done four years after the treaty comes into force. According to article 17 the treaty will come into force three months after 15 parties have deposited their instruments of ratification or accession to the treaty.

An important difference between this provision in the final act and the Basic Proposal is that the latter required the review to be done "no later than" four years after the treaty enters into force. The final act does not state a maximum period of time within which such review is to be done. This implies that the review is to be done four years **after** the treaty comes into force, and therefore such review could be held back for several years. This is similar to the review prescribed under article 71 of the TRIPS Agreement which has not been held till date.

9 Ibid.

10 South Centre, Statement to the WIPO Diplomatic Conference on a Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, 24 May 2024, available at https://www.southcentre.int/wp-content/uploads/2024/05/SC-Statement-WIPO-Treaty_24-May.pdf.

11 https://www.southcentre.int/wp-content/uploads/2024/05/South-Centre-Statement-WIPO-Diplomatic-Conference-on-GRs-TK.pdf

12 WTO document TN/C/W/59, 19 April 2011, available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/TN/C/W59.pdf&Open=True.

Article 8 also specifically mentions that the review will include extension of the disclosure requirement to derivatives. When read with article 3, this implies that derivatives as such are currently outside the scope of the disclosure requirement mandated under the treaty. Nevertheless, this should not prevent a contracting party from including derivatives within the scope of the disclosure requirement under its national law.

Article 8 read with article 3 also remains ambiguous about the issue of whether DSI are included within the scope of the disclosure requirement. While the reference to future review on including issues arising from new and emerging technologies in article 8 can consist of an extension of the mandatory disclosure requirement as a treaty obligation to DSI, this will not prevent any contracting party from including DSI within the scope of disclosure requirement under their law.

General principles on implementation

Article 9 of the treaty lays out the general principle that contracting parties will adopt measures necessary for the application of the treaty, and that nothing shall prevent them from determining the appropriate method of implementing the provisions of the treaty within their own legal systems and practices. This makes it clear that the treaty creates minimum standards and does not set maximum limits to the disclosure requirement under national laws. This is important because during the negotiations developed countries had pressed for the treaty to set both ceilings and floors to a globally harmonized disclosure requirement. An important issue is whether the countries that become parties to the treaty and that already provide for patent revocation or other broader requirements, will be bound to amend their regulations while becoming parties to the treaty.[13]

Treaty bodies

Article 10 of the treaty stipulates that the contracting parties of the treaty shall have an Assembly with powers on all matters relating to maintenance, development, application and operation of the treaty. Importantly, there is no provision in the treaty that empowers the Assembly to admit observers. This implies that non-contracting parties may not be admitted to the Assembly as observer States.

The WIPO Secretariat, or the International Bureau of WIPO, is stipulated to act as the treaty secretariat under article 11 of the treaty.

Revision and amendment

Article 14 of the treaty states that the treaty can be revised only by a Diplomatic Conference, in accordance with the Vienna Convention on the Law of Treaties (VCLT), and the Diplomatic Conference can only be convened by the treaty Assembly.

The reference to the VCLT in the final act was absent in the Basic Proposal. This reference was added in order to resolve a difference of views between developed and developing countries on whether non-contracting parties can participate in the Diplomatic Conference that would revise the treaty. During the negotiations at the Diplomatic Conference, the President's proposal that preceded the final act stated that the treaty can only be revised by a Diplomatic Conference of the contracting parties. This would have prevented any party that does not ratify the treaty or accede to it from participating in the revision of the treaty. The reference to the VCLT was added in this context based on a proposal by the US. However, it is worth noting that nothing in the VCLT regarding amendments of treaties allows non-parties to be part of the amendment or any other modification of a treaty, including revisions.

Essentially, this provision empowers the treaty Assembly to decide on whether non-contracting parties can participate in a Diplomatic Conference for revision of the treaty.

It is also important to note that article 15 of the treaty specifies the process for amendments to article 10 and 11 of the treaty by the Assembly, and does not allow non-contracting parties to be involved in this process. The Assembly also has not been given any discretion in this respect.

Denunciation and reservation

Article 19 of the treaty stipulates that a contracting party may denounce the treaty with a notice of one year to the WIPO Director-General, from the date of receipt. The denunciation shall not affect the application of the treaty to any patent application or granted patent in force in respect of the denouncing party at the time of coming into effect of the denunciation. Article 20 stipulates that there can be no reservations to the treaty.

Final remarks

The adoption of the historic international treaty on Intellectual Property, Genetic Resources, and Traditional Knowledge by WIPO marks a significant step forward for developing countries in establishing tools that can contribute to prevent or remedy the misappropriation of GRs and associated TK. Resulting from negotiations since 1999, the treaty mandates the disclosure of the origin or source of GRs and associated TK in patent applications, enhancing transparency of the patent system. Despite its narrower scope and limitations compared to some national laws, the treaty sets minimum disclosure standards and allows for broader national regulations. Its effectiveness will hinge on its rapid entry into force and a commitment to expand the scope of its coverage, signaling an important, but still insufficient, step towards a more equitable and transparent international patent system. It is also worth mentioning that, as noted by Flynn, the sophisticated and experienced leadership of ambassador Guilherme de Aguiar Patriota played a key role in the conclusion of the treaty negotiations.[14]

13 See Flynn, op.cit.: "Only two of the signatories (South Africa and Namibia) appear to allow revocation of patents as a standard remedy, suggesting that amendment of their domestic law may be required for them to ratify".

14 Ibid.

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The South Centre is the intergovernmental organization of developing countries that helps developing countries to combine their efforts and expertise to promote their common interests in the international arena. The South Centre was established by an Intergovernmental Agreement which came into force on 31 July 1995. Its headquarters is in Geneva, Switzerland.

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