

The WIPO Diplomatic Conference for a Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

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ABSTRACT

A new international legal instrument is set to be concluded under the auspices of the World Intellectual Property Organization (WIPO) in May 2024.¹ Its legal nature should be that of an international treaty, given that a Diplomatic Conference, the last treaty making stage, will be held for its conclusion. The purpose of the instrument (hereinafter “the Treaty”) is to create an international minimum standard for patent applicants to provide information concerning the origin or source of the genetic resources or traditional knowledge associated with genetic resources as part of the patent application process. This Policy Brief provides an overview of the rationale for the Treaty and of the process and substantive issues to be negotiated, and advances recommendations towards ensuring a successful conclusion of the Diplomatic Conference.

KEYWORDS: Diplomatic Conference, World Intellectual Property Organization (WIPO), Genetic Resources (GRs), Traditional Knowledge (TK), Intellectual Property (IP), Access and Benefit Sharing (ABS)

Un nouvel instrument juridique international devrait être conclu sous l'égide de l'Organisation mondiale de la propriété intellectuelle (OMPI) d'ici le 24 mai 2024. (1) Sa nature juridique devrait être celle d'un traité international, étant donné qu'une conférence diplomatique, dernière étape d'élaboration d'un traité, se tiendra pour sa conclusion. L'objectif de l'instrument (ci-après « le traité ») est de créer une norme minimale internationale pour les demandeurs de brevets afin qu'ils fournissent des informations concernant l'origine ou la source des ressources génétiques ou des connaissances traditionnelles associées aux ressources génétiques dans le cadre de la procédure de demande de brevet. Ce rapport sur les politiques donne un aperçu de la raison d'être du traité, du processus et des principaux éléments à négocier, et formule des recommandations visant à garantir une conclusion positive de la conférence diplomatique.

MOTS-CLÉS: Conférence diplomatique, Organisation mondiale de la propriété intellectuelle (OMPI), ressources génétiques, connaissances traditionnelles, propriété intellectuelle, l'accès et le partage des avantages

¹ See Viviana Muñoz Tellez, “A Breakthrough in Negotiations on Intellectual Property Protection of Genetic Resources and Traditional Knowledge in WIPO”, Policy Brief, No. 113 (Geneva, South Centre, 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/10/PB113_A-Breakthrough-in-Negotiations-on-Intellectual-Property-Protection-of-Genetic-Resources-and-Traditional-Knowledge-in-WIPO_EN.pdf; Nirmalya Syam, “WIPO Negotiations for an International Legal Instrument on Intellectual Property and Genetic Resources”, Policy Brief, No. 87 (Geneva, South Centre, 2021). Available from <https://www.southcentre.int/policy-brief-87-february-2021/>.

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KEY MESSAGES

The Treaty will provide a baseline for best practices in disclosure of information in patent applications on utilization of GRs and associated TK. This will improve transparency and legal certainty of the patent system.

The Treaty will provide an additional tool among those that can be applied to address the continued problems of misappropriation of GRs and associated TK and the unwarranted grant of patents that are based on GRs and associated TK.

Bajo los auspicios de la Organización Mundial de la Propiedad Intelectual (OMPI), se espera concluir un nuevo instrumento jurídico internacional el 24 de Mayo de 2024.⁽¹⁾ Su naturaleza jurídica debe ser la de un tratado internacional, dado que para su celebración se celebrará una Conferencia Diplomática, última etapa de la elaboración de un tratado. El objetivo del instrumento (en adelante «el Tratado») es crear una norma mínima internacional para que los solicitantes de patentes proporcionen información sobre el origen o la fuente de los recursos genéticos o los conocimientos tradicionales asociados a los recursos genéticos como parte del proceso de solicitud de patentes. El presente informe sobre políticas ofrece una visión general de los fundamentos del Tratado y del proceso y las cuestiones sustantivas que se negociarán, y formula recomendaciones para garantizar una conclusión satisfactoria de la Conferencia Diplomática.

PALABRAS CLAVES: Conferencia Diplomática, Organización Mundial de la Propiedad Intelectual (OMPI), recursos genéticos, conocimientos tradicionales, propiedad intelectual, el acceso y participación en los beneficios

I. The significance of the Treaty

The scope of the Treaty, in accordance with the Basic Proposal prepared by the WIPO Secretariat,² would be narrow. It would introduce an international obligation concerning patent applications based on genetic resources (GRs) or associated traditional knowledge (TK) and include a tool to improve the information available to patent offices in their prior art search when presented with patent applications for inventions that involve TK associated to GRs.

The Treaty would not affect any substantive aspects of patent law such as the criteria that an invention must meet to qualify for patent protection (i.e. novel, inventive step, industrial applicability). Yet with this limited scope, the Treaty is valuable.

For the international patent system, the international disclosure mechanism on GRs and associated TK will increase transparency, an important legal principle for the functioning of the patent system, while not unduly burdening patent offices. It will also signal the positive role that patent offices can play in upholding the public interest, in addition to supporting patent applicants.

Without requiring any additional work from patent offices, other than usual publication of patent applications, the information made available will be valuable in assisting the appropriate national authorities towards 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.

In this sense, the Treaty can be a significant step towards

² WIPO document GRATK/DC/3 available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=625814 (hereinafter "the Basic Proposal").

advancing measures within the international intellectual property (IP) system that help to increase synergy with existing international agreements regulating access to and the benefits arising from the utilization of GRs and associated TK³. It will establish an obligation for patent applicants to provide information on the origin or source of GRs or associated TK, including indigenous groups or local communities, that can support monitoring of and compliance with obligations that the Parties to the Treaty may have under the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD⁴.

The international disclosure requirement will not in itself be a direct tool to redress cases of misappropriation (utilisation of GRs and associated TK without compliance with national ABS legislation and legislation on TK protection). The requirement may nonetheless serve to alert to the research community, scientists, companies producing goods that utilize GRs and associated TK such as pharmaceuticals and cosmetics, that increased transparency is being required on the access to and utilisation of these resources, with the effect of encouraging adequate compliance with national ABS rules from the initial stages of bioprospecting and research and development.

If not the patent office, other appropriate authorities and stakeholders will be able to use the information provided pursuant to the disclosure obligation to monitor compliance with national ABS rules. Many countries already provide for national disclosure requirements concerning GRs and associated TK in patent applications and, therefore, there is already experience in how to implement such an obligation.⁵

The adoption of an international binding requirement should provide a baseline for best practices in this area, which will improve the overall functioning and legal certainty of the patent system, as all patent offices of the Parties to the Treaty will be bound to implement it regardless of differences in the procedures to grant a patent.

The patent office will only be required to develop a one-time guidance for patent applicants on how to inform on the country of origin or source of GRs and associated TK, when applying for inventions that utilize these resources. The information concerning GRs and associated TK will be disclosed as part of the regular patent application procedure. While not specifically provided for in the Basic

³ For a discussion on these and other agreements, see Nirmalya Syam et al., *Misappropriation of Genetic Resources and Associated Traditional Knowledge: Challenges Posed by Intellectual Property and Genetic Sequence Information*, Research Paper, No. 130 (Geneva, South Centre, 2021). Available from <https://www.southcentre.int/research-paper-130-april-2021/>.

⁴ See Viviana Munoz Tellez, "The Nagoya Protocol International Access and Benefit Sharing Regime", Policy Brief, No. 86 (Geneva, South Centre, 2020). Available from <https://www.southcentre.int/policy-brief-86-november-2020/>.

⁵ See Disclosure Requirements Table related to genetic resources and/or traditional knowledge. WIPO at https://www.wipo.int/export/sites/www/tk/en/docs/genetic_resources_disclosure.pdf.

Proposal, the information should be included in the patent application in order to make it publicly accessible upon publication of the application (normally after 18 months since the date of filing). Patent offices may set up other mechanisms to disseminate that information.

Moreover, for patent applicants, compliance with the disclosure mechanism would not be made burdensome in accordance with the draft provisions of the Basic Proposal. If the patent applicant does not provide the information or it is not duly disclosed, the opportunity is given to rectify or correct the patent application.

II. Procedural aspects of the Diplomatic Conference

The rules of procedure for the Diplomatic Conference have been agreed,⁶ and will be adopted formally at the beginning of the Conference. The composition of the country delegations now is a priority, and there is need to comply with the formalities of presenting credentials of the delegations, which may include full powers for signing the International Legal Instrument upon conclusion at the Conference, through letters sent to the WIPO Secretariat. These letters can be sent up to twenty-four hours prior to the Conference opening.

Several bodies will be established by the Conference to undertake the work. It is important that there are sufficient nominations for officers in the respective bodies, with balanced geographical representation. As the selection is an informal negotiation based on nominations, it is important to give priority to this process.

The Steering Committee is composed of the President and seven Vice-Presidents of the Conference, the President of the Credentials Committee, the Presidents of the Main Committees and the President of the Drafting Committee. The Committee has the critical role of proposing the text of any final act of the Conference (see draft Rule 1(2)(vi)), for adoption by the Conference.

Two main committees will be established, made up of all member States participating in the Conference, one for proposing the adoption by the Conference of the substantive provisions of the Treaty and any recommendation, resolution or agreed statement, and the second for proposing the adoption by the Conference of the administrative provisions and final clauses. It is important to note that both the substantive provisions and the administrative provisions and final clauses are all essential parts of a single document that will constitute the final text of the Treaty and, therefore, the negotiations in both main committees are equally of importance. The decision on acceptance of the finally agreed text must be done as a whole, based on agreement on all provisions of the Treaty.

⁶ See Draft Rules of Procedure of the Diplomatic Conference at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=617112.

The main committees can establish working groups that will each have a President and two Vice-Presidents. The establishment of working groups may be used to address particular issues that require further, more in depth discussion. However, working groups pose a unique challenge for inclusivity in negotiations, as smaller size delegations are not able to participate in various parallel processes. Therefore, a single negotiation process is preferable.

The Drafting Committee will prepare drafts and give advice on drafting as requested by either Main Committee, but it is not allowed to alter any texts submitted to it. It will be composed of seventeen elected officers and two ex-officio officers.

Decisions of all bodies should be made by consensus, as far as possible, but when not possible, can be taken by voting. Voting on certain issues such as the decision on whether to adopt the Treaty, requires two-thirds of the Member Delegations present and voting. For most decisions of all bodies, a simple majority is required with delegations present and voting. Proposals for amendment can be put to vote if seconded by at least one other Member Delegation.

III. The nature and substance of the Treaty

The Basic Proposal, which is the text for negotiation, does not specify the nature of the instrument. Given that a Diplomatic Conference is being held, as noted, the outcome should be a treaty that is legally binding on WIPO member States that become Parties.

The text of the Basic Proposal suggests that the obligations will be minimum requirements that Parties would be bound by, other than the provision in Article 6.3 concerning revocation or rendering unenforceable a patent because of non-compliance with the disclosure requirement.⁷ However, in the informal discussions different interpretations have been advanced as to whether Parties would be able to regulate aspects beyond the minimum standards in their domestic legislations. This has led to a proposal to clarify the issue under the Article 10 on general principles of interpretation. A shared understanding is yet to be established that the international disclosure requirement is aimed at establishing minimum baselines. This is important in particular for countries that currently or in the future will establish broader obligations, such as to provide evidence of compliance with ABS regulations and apply remedies (including the revocation of a patent) if the applicant bypassed such regulations.

There are two main substantive issues for consideration of the Diplomatic Conference. The first, as noted above,

⁷ The "Chairs notes text" to the Basic Proposal reveals that the text was not meant to establish ceilings unless specifically drafted for that purpose. See Notes to the Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, GRATK/DC/INF/4.

is an international mandatory disclosure requirement of the country of origin or source of a GR and TK associated to a GR. The second, is the optional development of databases containing information on TK to be shared with patent offices.

III.1. The disclosure requirement

Patent Applications

The Basic Proposal makes the mandatory requirement applicable to patent applications (article 3). The Draft Proposal provides for future review to consider extending to other forms of intellectual property rights (IPRs) (article 9).⁸ It will be important to add in the text of Article 3 that the disclosure should be made in the patent application.

Trigger

The trigger for the disclosure requirement, that is, to what claimed inventions is it applicable, is one of the still controversial issues that will be negotiated during the Diplomatic Conference. It is important to provide legal certainty to patent applicants, the relevant authorities and other stakeholders as to when the obligation applies.

Countries use a variety of formulations in their domestic disclosure requirements on this matter. A common formulation is “use” or “utilization” of GRs or TK associated to GRs. The Basic Proposal suggests the term “based on” with the qualifiers “materially” or “directly”. In the light of the accompanying definition provided for in the Basic Proposal,⁹ the addition of qualifiers to “based on” will narrow the trigger for when the disclosure requirement is applicable. The narrower the trigger, the less utility the disclosure requirement will provide for transparency purposes. As a general principle, if GRs are covered in the patent claims, the patent applicant should disclose the source and/or country of origin. If TK associated to GRs is covered in the patent claims, the patent applicant should disclose the indigenous people or local community from which the knowledge associated to GRs was obtained, or if this is not known, the source from which the knowledge was taken, such as a publication.

Definitions

The definition of the term GRs and associated TK is also an important issue subject to negotiation. The Basic Proposal includes a definition of GRs and genetic material.¹⁰

8 In accordance to Article 9 of the Basic Proposal, Parties “commit to a review of the scope and contents of this Instrument, addressing issues such as the possible extension of the disclosure requirement in Article 3 to other areas of intellectual property no later than four years after the entry into force of the Instrument”.

9 The definition reads: “[Materially/Directly] based on” means that the GRs and/or TK associated with GRs *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 GRs and/or TK associated with genetic resources*”.

10 “Genetic resources” is defined as “genetic material of actual or potential value”. “Genetic material” is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity”. These follow the definitions con-

No definition of TK associated to GRs is provided, as there is current no internationally accepted definition although there is a general understanding based on the CBD Article 8(j)¹¹ and the draft definition developed in the WIPO Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC)¹². If the disclosure requirement applies only to GRs and genetic material as defined in the Basic Proposal, then patent applicants would not be required to disclose the origin or source of the biochemical components of GRs on which an invention could be based on, that is, derivatives.¹³

While the Basic Proposal would provide for a future review after four years after entry into force of the Treaty (article 9) and this could provide an opportunity to include derivatives, it is important to note that many products are made using derivatives of GRs and associated TK on their properties and hence it would be desirable to include them now in the scope.

Likewise, the Basic Proposal does not expressly include digital sequence information (DSI) on GRs as a part of the disclosure requirement, nor mention to DSI is made among the areas for possible review after four years of entry into force of the agreement towards “addressing other issues arising from new and emerging technologies that are relevant” (article 9). Synthetic biology has advanced significantly, and there are numerous patents in relation to genetic sequences of deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins (amino acids). Increased transparency in the patent system would be achieved with disclosure of the origin or source of DSI on GRs.¹⁴ There may be no need to define DSI in the Treaty.¹⁵

Exceptions and Limitations

The Basic Proposal includes a provision allowing for Parties to the Treaty to adopt exceptions and limitations to the disclosure requirement when necessary to protect

tained in the Convention on Biological Diversity.

11 Article 8(j) of the Convention on Biological Diversity refers to traditional knowledge as “knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles” related to genetic resources.

12 The draft articles developed under the framework of the WIPO Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) towards developing an international instrument on the protection of traditional knowledge define traditional knowledge as “knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that is dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning.” See WIPO document WIPO/GTRKF/IC/47/4.

13 The Nagoya Protocol defines “derivatives” as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity” (Article 2(e)).

14 In the context of the Convention on Biological Diversity, the Conference of Parties has agreed to develop a multilateral system for the sharing of benefits derived from the utilization of DSI on GRs.

15 This could mirror the solution adopted under the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ) for regulating ABS for utilization of DSI on marine biological diversity of areas beyond national jurisdiction. DSI is included in the scope of the obligations in the text, the term remains undefined.

the public interest (article 4). In no national legislation has the disclosure requirement been subject to limitations and exceptions, primarily because it is not creating any rights. There does not seem to be a good reason for the inclusion of this provision in the Basic Proposal, and none is provided in the explanatory notes to the text.¹⁶ In the negotiations, deletion of the article would be appropriate, as it is not relevant to the international disclosure mechanism.

Sanctions and Remedies

The Basic Proposal in Article 9 requires that Parties allow the applicant to rectify a failure to comply with the disclosure obligation before the application of sanctions or directing remedies and provides flexibility on the type of measures that the Parties can adopt to address non-compliance by patent applicants, provided that the measures are appropriate, effective and proportionate. The main elements for negotiation during the Diplomatic Conference will be Article 6.3 and 6.4 concerning whether Parties can revoke a patent as a sanction for non-compliance when there has been fraudulent intention. This flexibility should be allowed in national legislation, given that the ground for revocation would be narrowed to situations of fraudulent intention, and it is in accordance with current international rules under the WIPO Patent Law Treaty, Article 10. For greater clarity, Article 6.3 text “subject to” should be modified by “without prejudice to”.

III.2 Information Systems

The second substantive aspect of the Basic Proposal concerns the voluntary establishment of databases or other information systems of GRs and TK associated to GRs (article 7). Parties may establish and make these accessible to patent offices for the purposes of search and examination of patent applications, which may be subject to authorization, with the aim of facilitating the prior art search by patent examiners (article 7) and avoid the grant of a patent to a claimed invention which does not meet the criteria of novelty and/or inventive step.

No obligation is created for Parties to establish information systems. However, a process is defined for possible future work, including on developing interoperability standards and structures of the content of the information systems, principles and modalities for the sharing of information related to GRs and TK associated to GRs, and for an online portal to be hosted by WIPO through which offices could access directly and retrieve data from these information systems.

The development of information systems on GRs and TK associated to GRs is a contentious issue, requiring careful elaboration of safeguards, in depth consultations with national authorities regulating access and utilization of GRs

and TK associated to GRs, as well as of TK holders. Moreover, these activities require significant resources. The Basic Proposal does not provide for any form of international cooperation or support by the WIPO Secretariat towards assisting in the implementation of this article.

III.3 Review and revision

As noted above, the Basic Proposal provides in Article 9 for the review of the scope and contents of the Treaty, for issues that can include the extension of the disclosure requirement to other areas of IPRs beyond patents and to include derivatives. The Basic Proposal also provides for possible revision of the Treaty once adopted, in Article 12. As per usual practice in WIPO treaties and international law of treaties, the Assembly that is made up of the Parties of the Treaty would decide on the matters of review and revision of the Treaty.

There is an effort by some countries to suggest that these matters of review and revision should not be open only to contracting Parties of the Treaty, but to the broader WIPO membership. This proposal would risk setting a negative international precedent and potentially work against the achievement of the objectives of the Treaty.

IV. Conclusions

The success of the Diplomatic Conference will depend on the ability of developing countries to coordinate their positions so that the final text of the Treaty contains the necessary minimum elements to serve its purpose, while striking a compromise with other WIPO member States that have historically been reticent to advance an international disclosure mechanism for GRs and associated TK.

The new Treaty, as a binding instrument with a majority of WIPO member States becoming Parties, will serve as an important tool within the international patent system towards supporting transparency and recognition of the social and economic value of TK, among others.

If the Diplomatic Conference is successful, the next step will be to advance on the signature and ratification of the Treaty by WIPO member States so that there is a sufficient number of Parties for it to enter into force. Countries should proceed swiftly towards ratification in order to allow the Treaty to come into force. This will be of particular importance in the case of countries that do not currently require patent applicants to disclose the origin or source of GRs and associated TK. The timing is also important to maintain the momentum for domestication of the instrument. In parallel to signature and ratification, countries will need to begin, with support of the WIPO Secretariat and other institutions that provide technical advice such as the South Centre, to put in place the necessary measures domestically to implement the Treaty

¹⁶ See the WIPO document, footnote 7.

provisions in a way that is most appropriate to achieve the goals of the Treaty taking into account differences in legal systems. This process will require policy attention and dedicated resources. It will also require consultations among relevant Ministries and other national authorities for an effective operationalisation of the Treaty provisions.

The Treaty should be viewed as one additional tool among those that can be applied to address the continued problems of misappropriation of GRs and associated TK and the unwarranted grant of patents that are based on GRs and/or associated TK. It will also contribute to advance the recognition of the rights of indigenous peoples in respect to their TK, an issue that is beyond the scope of the Treaty. WIPO provides a forum for discussions on this issue to continue, as agreed by the WIPO General Assembly in 2023 in the ad-hoc intergovernmental working group on IP, GRs, TK and Folklore (IGC). However, WIPO is not the only or arguably the best suited forum to discuss solutions to the range of aspects of these complex issues, which should continue to be pursued in parallel in other fora.

The WIPO Secretariat should be asked to present the Treaty, if adopted, to the Conference of the Parties of the

CBD and the Nagoya Protocol in December 2024, to promote its adoption and identify synergies with the implementation of CBD-Nagoya legal framework.

Subsequently, WIPO Parties to the Treaty should bring forward an agenda to the Patent Cooperation Treaty (PCT) to make the necessary amendments to provide for an international disclosure requirement on GRs and associated TK. This will ensure that the disclosure requirement is applicable in more jurisdictions, particularly in WIPO member States that have not ratified the Treaty but are party to the PCT. This is consistent with the approach suggested in the Basic Proposal for an agreed statement (article 8, footnote 2).¹⁷

¹⁷ Agreed Statement to Article 8: The Contracting Parties request the Assembly of the International Patent Cooperation Union to consider the need for amendments to the Regulations under the PCT and/or the Administrative Instructions thereunder 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.

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