



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-C-2024-0048]

Request for Comments and Testimony on the World Intellectual Property

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

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for comments and notice of hearing.

SUMMARY: The United States Patent and Trademark Office (USPTO), Department of Commerce, requests input from all interested parties on the World Intellectual Property Organization (WIPO) Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (hereinafter, “the Treaty”) adopted by WIPO Member States in Geneva, Switzerland on May 24, 2024. In particular, the USPTO welcomes written comments, and will hold a hybrid hearing, on whether the United States should sign and implement the Treaty and any impacts of taking those actions. The text of the Treaty can be found on the WIPO website at:

https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_7.pdf.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The USPTO will also hold a hybrid hearing on this matter on April 29, 2025, from 9 a.m.-12 p.m. and 1-4 p.m. eastern time (ET). If necessary, the hearing may continue on April 30, 2025. Any interested parties wishing to present oral testimony at the hearing must submit a written request for an opportunity to do so no later than April 22, 2025. Details on submitting such a request are provided below.

ADDRESSES:

I. For Comment Submitters

For reasons of Government efficiency, comments should be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>. To submit comments via the portal, enter docket number PTO-C-2024-0048 on the homepage and select “Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for information and select the “Comment” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in Adobe® portable document format or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as a personal address or phone number, should not be included.

Visit the Federal eRulemaking Portal (www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please submit comments by First-Class Mail or Priority Mail to: Michael Buckler, Patent Attorney, Mail Stop OPIA, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

II. For All Hearing Attendees

The hybrid hearing will be held in person in the Clara Barton Auditorium at the USPTO, 600 Dulany Street, Alexandria, Virginia 22314. The hearing will also be available in a virtual format for those wishing to attend remotely. Prior to the hearing, information on attendance will be posted on the Office of Policy and International Affairs (OPIA) section of the USPTO website, <https://www.uspto.gov/ip-policy>.

III. For Hearing Testifiers (Requests to Present Oral Testimony)

All interested parties are invited to testify at the hearing. Anyone wishing to present oral testimony at the hearing must submit a request in writing no later than April

22, 2025. Requests to testify must be submitted by email to Michael Buckler at michael.buckler@uspto.gov or, if email submission is not feasible due to a lack of access to a computer and/or the internet, by First-Class Mail or Priority Mail as indicated above.

Requests to testify should specify:

1. The name of the person wishing to testify;
2. The person's contact information (telephone number and email address);
3. The organization(s) the person represents, if any;
4. An indication of the amount of time needed for the testimony (not to exceed 5 minutes to allow time for follow-up questions);
5. An indication of whether testimony will be provided in person or remotely; and
6. A copy of your prepared remarks.

FOR FURTHER INFORMATION CONTACT: Michael Buckler, Patent Attorney, USPTO, Office of Policy and International Affairs (OPIA), at michael.buckler@uspto.gov (preferred) or 571-272-6024.

SUPPLEMENTARY INFORMATION:

I. Background

WIPO is a specialized United Nations agency based in Geneva, Switzerland, that focuses on intellectual property. Established in September 2000, the WIPO Intergovernmental Committee (IGC)¹ is a Permanent Committee of WIPO where Member States² and accredited observers can discuss and address intellectual property issues that arise in the context of access to genetic resources (GRs) as well as the

¹ More information on the IGC may be found at: <https://www.wipo.int/tk/en/igc>.

² WIPO currently has 193 Member States. <https://www.wipo.int/members/en/>.

protection of traditional knowledge (TK) and traditional cultural expressions (TCEs). The IGC operates in accordance with a mandate³ determined by the WIPO General Assembly.

At its Fifty-Fifth (30th Extraordinary) Session, held in Geneva on July 14-22, 2022, the WIPO General Assembly decided to convene a diplomatic conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

The diplomatic conference occurred on May 13-24, 2024, at WIPO Headquarters in Geneva. On May 24, 2024, WIPO Member States adopted the Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge. The text of the adopted Treaty is different in several respects from the proposed text⁴ that served as the starting point for negotiations at the diplomatic conference.

Article 3 of the Treaty mandates that patent applicants disclose the origin/source of a GR, or associated traditional knowledge (ATK) provided by Indigenous Peoples or local communities, in certain circumstances. In particular, the disclosure requirement is triggered where a claimed invention is “based on” a GR or ATK, which requires satisfaction of a two-part test: (1) the GR or ATK “must have been necessary for the claimed invention”; and (2) “the claimed invention must depend on the specific properties of” the GR or ATK. Among its 22 articles, the Treaty covers several other topics, including treaty objectives, definitions, exceptions and limitations, non-retroactivity, sanctions and remedies for noncompliance, relationship with other international agreements, and review and potential revision of Treaty text.

³ The current “IGC Mandate”, covering the biennium 2024/2025, may be found at: <https://www.wipo.int/export/sites/www/tk/en/igc/docs/igc-mandate-2024-2025.pdf>.

⁴ That text (known as the “Basic Proposal”) may be found at: https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_3.pdf. In October 2023, following a Special Session and Preparatory Committee meeting of the IGC, the USPTO requested comments on draft text that subsequently became the “Basic Proposal” of the diplomatic conference. <https://www.federalregister.gov/documents/2023/10/24/2023-23387/wipo-igc-negotiations-on-genetic-resources-and-associated-traditional-knowledge>. Comments received by the USPTO helped inform positions taken by the United States at the diplomatic conference.

For additional context, the text of the Treaty can be found on the WIPO website at: https://www.wipo.int/edocs/mdocs/td/en/gratk_dc/gratk_dc_7.pdf. Likewise, WIPO's "informal summary" of the Treaty can be found at:

https://www.wipo.int/edocs/mdocs/mdocs/en/gratk_dc/gratk_dc_exsum.pdf.

The Treaty is open for signature for one year after its adoption (i.e., up to May 23, 2025).⁵ The act of signing does not make a Member State a party to (i.e., bound by) the Treaty. Rather, signing qualifies the signatory Member State to proceed to ratification, acceptance, or approval; and creates an obligation for the Member State to refrain from acts that would defeat the object and purpose of the Treaty.⁶ To become a party to the Treaty, a Member State must undertake a separate step of ratification or accession.⁷

The Treaty will enter into force three months after it is ratified or acceded to by 15 eligible parties.⁸ Thereafter, Treaty provisions will apply in any Member State of WIPO that is or subsequently becomes a Contracting Party to the Treaty. This means, for example, that the Treaty's required disclosure of the origin/source of GRs/ATK will apply to all patent applicants who file an application in a Contracting Party, including those applicants who come from countries that have not ratified or acceded to the Treaty.

Within the U.S. Government, the USPTO, based on authority delegated by the U.S. Department of State, takes the lead in the WIPO IGC among other Federal agencies and coordinates and develops U.S. positions on issues before the WIPO IGC.

⁵ According to WIPO, as of December 5, 2024, thirty-eight delegations had signed the Treaty: Algeria, Bosnia and Herzegovina, Brazil, Burkina Faso, Cabo Verde, Central African Republic, Chile, Colombia, Congo, Côte d'Ivoire, Democratic People's Republic of Korea, Dominican Republic, Eswatini, Gambia, Ghana, Indonesia, Lesotho, Madagascar, Malawi, Marshall Islands, Morocco, Namibia, Nicaragua, Niger, Nigeria, Niue, Paraguay, Peru, Saint Vincent and the Grenadines, Sao Tome and Principe, Senegal, South Africa, Togo, United Republic of Tanzania, Uganda, Uruguay, Vanuatu, and Zimbabwe. <https://www.wipo.int/export/sites/www/treaties/en/docs/pdf/gratk.pdf>.

⁶ See, e.g., Article 18 of the Vienna Convention on the Law of Treaties. https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

⁷ See WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, Articles 12-13, 18. https://www.wipo.int/edocs/mdocs/td/en/gratk_dc/gratk_dc_7.pdf.

⁸ According to WIPO, as of December 5, 2024, only Malawi had ratified or acceded to the Treaty.

In addition to this request for comments and notice of hearing, the USPTO will conduct a Tribal Consultation to seek input from Tribes on the Treaty. Additional details about the Tribal Consultation can be found in a notice published in this issue of the Federal Register.

II. Substantive Guidance on Comments and Testimony

The USPTO welcomes any relevant, written comments or oral testimony on the topics described herein, particularly on the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, the text of which can be found on the WIPO website at:

https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_7.pdf.

The USPTO is especially interested in responses to the questions below. However, commenters or testifiers need not respond to every question and may provide relevant information even if it is not responsive to a particular question. Comments and testimony should be as detailed as possible and provide all necessary information to enable an objective assessment of the views expressed, including specific references to: laws, regulations, and policy statements; executive, presidential, or other orders; administrative, court, or other determinations; and available data (and associated methodology) regarding purported and potential impacts of policy decisions.

1. In your view, should the United States sign and become a party to the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge? In your response, please identify and explain your reasoning in detail, including legal and policy considerations.
2. In your view, please explain whether the Treaty is consistent with existing U.S. patent law. In your response, please explain your legal reasoning and identify the provision(s) of the Treaty that you view as consistent or inconsistent with U.S. patent law.

3. If, in your view, the Treaty is inconsistent with existing U.S. patent law, please identify and explain the change(s) to U.S. patent law necessary for compliance with the Treaty. In doing so, please describe any impact(s) of adopting such changes.
4. In your view, please explain whether the Treaty is consistent with existing U.S. international obligations, including treaties, free trade agreements, and other binding international agreement(s). In your response, please explain your legal reasoning and identify any provision(s) of the Treaty that you view as consistent or inconsistent with specific U.S. international obligations.
5. If the United States does not become a party to the Treaty, please identify any Treaty provision(s) you believe should be incorporated into U.S. patent law. In your response, please explain the reason(s) for and any impact(s) of incorporating the identified provision(s) into U.S. patent law.
6. In your view, please identify and explain any impact(s) of implementing the Treaty in the United States on domestic and global innovation, including U.S. science and innovation leadership.
7. In your view, please identify and explain any impact(s) of implementing the Treaty in the United States on businesses, consumers, investors, and the economy.
8. Based on your experiences with other countries that require patent applicants to disclose the source or origin of GRs or ATK, please identify and explain any possible impact(s) of Treaty implementation in the United States.

III. Additional Information on Hearing

Speaking slots are limited, and the USPTO may be unable to honor all requests.

If more requests to provide oral testimony are received than time allows, requesters will be invited to submit written comments. Time slots will be a maximum of five minutes each to allow for follow-up questions on testimony or corresponding comments. Speakers

providing testimony at the hearing should submit a written copy of their testimony for inclusion in the record of the proceedings no later than April 22, 2025. Speakers will have one week following the hearing to submit any supplemental materials referenced during their testimony. Such materials must be submitted by email to Michael Buckler at michael.buckler@uspto.gov or, if email submission is not feasible due to a lack of access to a computer and/or the internet, by First-Class Mail or Priority Mail as indicated above.

Before the hearing, an agenda of witness testimony will be sent to testifiers and posted on the OPIA section of the USPTO website, <https://www.uspto.gov/ip-policy>.

If time allows, the USPTO may permit unscheduled testimony at the hearing.

The hearing will be physically accessible to people with disabilities. Individuals requiring accommodation, such as sign language interpretation or other ancillary aids, should communicate their needs to the person listed in the FOR FURTHER INFORMATION CONTACT section of this notice at least seven business days prior to the hearing.

A recording of the hearing will be posted on the OPIA section of the USPTO website, <https://www.uspto.gov/ip-policy>, as soon as possible after the hearing.

A transcript of the hearing will be available on the OPIA section of the USPTO website, <https://www.uspto.gov/ip-policy>, as soon as possible after the hearing.

Derrick L. Brent,

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office.

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