DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-C-2024-0049]

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

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

ACTION: Notice of Tribal Consultation and request for written comments.

SUMMARY: The United States Patent and Trademark Office (USPTO), Department of Commerce, announces a Tribal Consultation, and requests written comments, regarding the World Intellectual Property Organization (WIPO) Treaty on Intellectual Property, Genetic Resources (GRs) and Associated Traditional Knowledge (ATK) (hereinafter, the "Treaty") adopted by WIPO Member States in Geneva, Switzerland on May 24, 2024. The Tribal Consultation will consist of virtual webinars and a request for written comments on whether the United States should sign and implement the Treaty and any impacts of taking those actions. For purposes of this Notice, the words "Tribe" or "Tribes" are intended to refer to Tribal Nations, State recognized Tribes, other Tribes, and Native Hawaiians and other Pacific Islanders.

DATES:

Webinar Dates: The two virtual webinars for federally recognized Tribal Nations and their proxies will be held on Tuesday, March 18 and Wednesday, March 19, 2025, 3 p.m. to 5 p.m. (eastern). The virtual webinar for the Native Hawaiian Community, their representatives and organizations, and other Pacific Islanders will be held on Thursday, March 27, 2025, 3 p.m. to 5 p.m. (eastern). The virtual webinar for State and non-recognized Tribes, and Tribal and inter-Tribal organizations, including organizations that represent Indigenous Peoples based in the United States, will be held on Friday, March 28, 2025, 3 p.m. to 5 p.m. (eastern).

Written Comment Deadline: Written comments on the questions in this Notice must be received by Monday, April 28, 2025.

Address: Webinar Registration Address: Please register in advance to participate in one of these webinars at: https://www.uspto.gov/ip-policy/tribal-consultations-genetic-resources-traditional-knowledge-and-traditional-cultural. After registering, you will

receive a confirmation email containing information about joining the meeting. If you are unable to join via the platform, a call-in number also will be provided. The registration links are not the same for each webinar.

Written Comments Address: Written comments may be submitted by email to: TribalConsult2025_GRATKTreaty@uspto.gov. Please use the heading "WIPO GRATK TREATY TRIBAL CONSULTATION 2025" in the subject line. Please note: Tribes must submit written comments responsive to the issues raised in this Notice and/or the public FRN by Monday, April 28, 2025.

If electronic submission of comments is not feasible, please submit comments by First-Class Mail or Priority Mail to: Susan Anthony, Tribal Affairs Liaison, Mail Stop OPIA, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22314–1450.

FOR FURTHER INFORMATION CONTACT:

Susan Anthony, Tribal Affairs Liaison, Office of Policy and International Affairs (OPIA), USPTO, at Susan. Anthony@uspto.gov or 571–272–8459. Please direct media inquiries to the USPTO's Office of the Chief Communications Officer at 571–272–8400. These webinars are closed to the media.

SUPPLEMENTARY INFORMATION: 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 serves as a forum where WIPO Member States 2 and accredited observers can discuss and address the intellectual property issues that arise in the context of access to GRs as well as the protection of traditional knowledge (TK) and traditional cultural expressions (TCEs). The IGC operates in accordance with a mandate 3 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, Switzerland. On May 24, 2024, WIPO Member States adopted the Treaty. The text of the adopted Treaty is different in several respects from the proposed text ⁴ 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, nonretroactivity, sanctions and remedies for noncompliance, relationship with other international agreements, and review and potential revision of Treaty text.

For additional context, 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. 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 by any eligible Member State of WIPO for one year after its adoption (*i.e.*, up to May 23, 2025).⁵ The act of signing does

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¹ More information on the IGC may be found at: www.wipo.int/tk/en/igc. In particular, 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

² WIPO currently has 193 Member States (www.wipo.int/members/en/).

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). Tribal input received by the USPTO helped inform positions taken by the United States at the diplomatic conference.

⁵ According to WIPO, as of December 5, 2024, 38 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, Zimbabwe.

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. To become a party to the Treaty, a Member State must undertake a separate step of ratification or accession.

The Treaty will enter into force three months after it is ratified or acceded to by 15 Contracting 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.

Request for Information

The USPTO welcomes Tribal input on any issues relevant to this Notice and is particularly interested in comments responsive to the questions below. The USPTO also has issued in this issue of the Federal Register a notice entitled, "Request for Comments and Testimony on the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge," which is directed to the general public ("public FRN"). Tribes may also provide comments responsive to the questions or participate in the public hearing described in the USPTO's public FRN regarding the Treaty.

Questions for Comment

When submitting written comments, please identify yourself and either your Tribal Government, or that you are a Native Hawaiian or other Pacific Islander. If you are a representative, please identify yourself and for whom

(https://www.wipo.int/export/sites/www/treaties/en/docs/pdf/gratk.pdf).

you are speaking. Commenters need not respond to every question and may provide relevant information, even if not responsive to a particular question.

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 reasons in detail, including legal, policy, and any other considerations.

2. In your view, please explain whether the Treaty is consistent or inconsistent with existing U.S. law, including tribal treaties and other federal law. In your response, please explain your legal reasoning and identify the provisions of the Treaty that are consistent or inconsistent with U.S. law.

3. If, in your view, the Treaty is inconsistent with existing U.S. law, please identify and explain the change(s) to U.S. law necessary for compliance with the Treaty. In doing so, please describe any impacts of adopting such change(s).

4. In your view, please explain whether the Treaty is consistent or inconsistent with existing U.S. international obligations, including treaties, free trade agreements, and other international agreement(s). In your response, please explain your legal reasoning and identify the provision(s) of the Treaty that are consistent or inconsistent with specific U.S. international obligations.

5. Please indicate whether and, if so, how GRs and ATK may be protected by existing U.S. law(s). In doing so, please explain your legal reasoning and identify the specific law(s) by which GRs and ATK may be protected.

6. Please indicate whether and, if so, how GRs and ATK may be protected by tribal treaties, tribal customary law and protocols, tribal codes, or in other ways. In doing so, please explain your legal reasoning and identify the specific provision(s) of the identified ways by which GRs and ATK may be protected.

7. If the United States does not become a party to the Treaty, please identify any Treaty or other provision(s) you believe should be incorporated in U.S. patent or other law for protection of GRs and ATK. In your response, please explain the reason(s) for and any impact(s) of, incorporating those provisions in U.S. patent or other law.

8. In your view, please identify and explain any impact(s) of implementing the Treaty on domestic and global innovation, including both tribal and non-Indigenous innovation.

9. 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.

10. In your view, please identify and explain any impact(s) of implementing or not implementing the Treaty on the Tribal Nations and other Indigenous Peoples located in the U.S.

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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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 March 18, 2025. 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.

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/tk/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.