



## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

[Docket No.: PTO-C-2023-0019]

### WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge

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

**ACTION:** Notice and request for comments.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), Department of Commerce, requests public comments on certain text-based negotiations before the World Intellectual Property Organization (WIPO) Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (Traditional Cultural Expressions). WIPO will organize a diplomatic conference to negotiate a treaty focusing on intellectual property (IP), genetic resources (GRs), and traditional knowledge (TK) associated with GRs no later than 2024. Public comments are requested regarding the negotiations on genetic resources and associated traditional knowledge.

**DATES:** The written comment period will begin on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and end on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** 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-2023-0019 on the homepage and click “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 click on 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 an address or phone number, should not be included.

Visit the Federal eRulemaking Portal ([www.regulations.gov](http://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: Paolo M. Trevisan, Patent Attorney, Mail Stop OPIA, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

**FOR FURTHER INFORMATION CONTACT:** Paolo M. Trevisan, Patent Attorney, USPTO, Office of Policy and International Affairs (OPIA), at 571-272-7110.

**SUPPLEMENTARY INFORMATION:**

WIPO is a specialized United Nations agency based in Geneva, Switzerland, that focuses on intellectual property. Established in September 2000, the WIPO IGC serves as a forum where WIPO Member States<sup>1</sup> and accredited observers can discuss and address the intellectual property issues that arise in the context of access to GRs and benefit-sharing as well as the protection of TK and traditional cultural expressions (TCEs).

Since 2009, the WIPO IGC has been engaged in separate text-based negotiations on (1) an international legal instrument for the protection of genetic resources and associated traditional knowledge and (2) an international legal instrument for TK and TCEs. The United States understands the term “international legal instrument” in the WIPO IGC mandate<sup>2</sup> to include declarations, recommendations, best practices, toolkits, and other forms of “soft law” and actively

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<sup>1</sup> WIPO currently has 193 Member States ([www.wipo.int/members/en/](http://www.wipo.int/members/en/)).

<sup>2</sup> The current “IGC Mandate” may be found at: Intergovernmental Committee (IGC) ([wipo.int](http://wipo.int)) ([www.wipo.int/tk/en/igc](http://www.wipo.int/tk/en/igc)). The current IGC Mandate covers the biennium 2024/2025. <https://www.wipo.int/export/sites/www/tk/en/igc/docs/igc-mandate-2024-2025.pdf>

seeks a practical outcome. WIPO also has the authority to initiate norm-setting discussions and to propose international rules for adoption by a diplomatic conference or by another WIPO body. Thus the phrase “international legal instrument(s)” could also include a treaty or international agreement, although there is no requirement that prescribes this particular outcome.

During the 42<sup>nd</sup> and 43<sup>rd</sup> sessions of the WIPO IGC held in Geneva in 2022, the IGC completed its designated sessions on Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources for the 2022/2023 biennium. These sessions made some progress and achieved a level of convergence around document WIPO/GRTKF/IC/43/4, the “Consolidated Document Relating to Intellectual Property and Genetic Resources” (the consolidated text). The consolidated text had been drafted and revised through negotiations between the WIPO Member States over an extended period of time, during multiple meetings of the IGC. This document reflected the many divisions and differences of views on key concepts and definitions among the participants to the sessions.

The previous Chair of the IGC, Mr. Ian Goss of Australia, drafted document IPO/GRTKF/IC/43/5, the “Chair’s Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources” (the Chair’s text), on his own authority, based on his interpretation of discussions between Member States.

The current Chair, Ms. Lilyclaire Bellamy of Jamaica, made the Chair’s text available to Member States during IGC 43 as a text for discussion but not for negotiation. Both the Chair’s text and the consolidated text include provisions for a mandatory disclosure requirement of the country of origin/source of genetic resource(s) in a patent application where the claimed invention is based on genetic resources. While the term GR is defined

in the Convention on Biological Diversity (CBD)<sup>3</sup> as “all genetic material of actual or potential value,” and that definition is used in the non-negotiated Chair’s text with the footnote that it is “. . . not intended to include “human genetic resources”.” , the term GR has not been given an agreed definition in the consolidated text.

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, based on document WIPO/GRTKF/IC/43/5 (the Chair’s text) and any other contributions by Member States. The diplomatic conference is to be held in 2024.

A Preparatory Committee of the Diplomatic Conference was convened in September 2023 to establish the procedures for the diplomatic conference and also consider “administrative provisions and final clauses” of the instrument drafted by the WIPO Secretariat (Articles 10 through 23). A special session of the IGC was also convened in September 2023, preceding the Preparatory Committee, to close any existing gaps in “substantive articles” (Articles 1 through 9) of the Chair’s text to the extent possible. The Preparatory Committee and special session concluded with the adoption of rules of procedure for the diplomatic conference but with only minor changes to the “substantive articles” of the Chair’s text and “administrative provisions and final clauses” from the WIPO Secretariat, reflecting the significant differences in interests between the parties involved, which will have to be addressed in further negotiations at next year’s diplomatic conference.

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<sup>3</sup> See Article 2 in [Home | Convention on Biological Diversity \(cbd.int\)](https://www.cbd.int) (www.cbd.int). The United States is not a member of the CBD, but accepts these definitions for purposes of the work in the WIPO IGC.

Within the U.S. Government, the USPTO, based on authority delegated by the State Department, takes the lead in the WIPO IGC among other Federal agencies and coordinates and develops U.S. positions on issues before the WIPO IGC. The text-based negotiations before the WIPO IGC include the protection of genetic resources and associated traditional knowledge. These negotiations may result in changes to requirements for filing patent applications and for challenging patent rights.

The WIPO IGC will also continue its text-based negotiations on IP and the protection of TK and TCEs to the renewed mandate of the IGC for the biennium 2024/2025 as decided by the WIPO General Assembly at the 64th Series of Meetings of the Assemblies of the Member States of WIPO held July 6 – 14, 2023.

### **Request for Comments**

This request for comments seeks public and stakeholder input to inform U.S. Government participation in the ongoing WIPO IGC meetings and in anticipation of a diplomatic conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, expected to be held in 2024.

In addition, this request for comments seeks input to inform the U.S. Government as it participates in the ongoing WIPO IGC meetings on TK/TCEs.

The following is particularly useful in forming an understanding of the issues under discussion, and in answering the questions below.

Both the Chair's text and the consolidated text include provisions for mandatory disclosure requirements of the country of origin or source of GR and associated TK (ATK) in a patent application where the claimed invention is based on GR. Article 29.1 of the TRIPS Agreement provides that TRIPS member countries must require a patent applicant to disclose the invention in a manner that is sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The term "disclosure

requirements,” which is expected to be addressed by the diplomatic conference, generally refers to additional requirements that would include the source or origin of the GR and associated TK as part of the patent application. Details of the disclosure requirements have not been agreed to as part of the Chair’s text nor the consolidated text.

These additional requirements to disclose the source or origin of the GR and associated TK as part of a patent application involve a number of issues that likely will be the subject of negotiations at the upcoming diplomatic conference, some of which are highlighted below.

#### A. Definition of Genetic Resources

“Genetic resources” are defined in the Convention on Biological Diversity (CBD) as “genetic material of actual or potential value” wherein “genetic material” is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.” Agreement has yet to be reached by the IGC on the definition of “genetic resources” in the Chair’s text or the consolidated text.

#### B. Content of Disclosure

The content of what is required to be disclosed in a patent application with respect to the mandatory disclosure requirements has been the topic of much debate in the IGC negotiations. Under different versions, patent applicants may be required to disclose:

- the country of origin of the GRs;
- the source of the GRs (for example, a gene bank that provided genetic material);
- the legal provenance of the GRs (the chain of custody pursuant to legal authority);
- the legal status of the GRs and/or ATK, such as compliance with any legal obligations relating to access and benefit-sharing or prior informed consent for accessing and using GRs; and
- a due diligence declaration that the applicant has complied with all applicable legal requirements concerning access to and use of GRs and/or ATK.

Agreement has yet to be reached on the definition of “content.”

### C. Disclosure Triggers

The application of patent disclosure requirements in the Chair’s text and the consolidated text is dependent on a “trigger” or link between the claimed invention and relevant GRs or ATK – that is, the relationship with the subject matter of disclosure.

The trigger may bring about or give rise to the disclosure requirements in response to various situations, such as:

- whether the GR/ATK is incidental or material to the development of the invention;
- whether the GR/ATK is necessary to assess, understand, replicate, or carry out the invention, or the GR/ATK is in effect only a vehicle for a separate innovative concept;
- whether the GR/ATK contributes to one earlier step in a chain of innovations that over time culminated in the invention, or is a direct input to the claimed inventive step;
- whether particular qualities of the GR/ATK are essential to the invention; and
- whether a GR/ATK is used in a particular embodiment or one example in a description of the invention, but is not indispensable to arrive at or replicate the invention as claimed.

There has yet to be agreement on a definition of the “trigger.”

### D. Remedies and Sanctions

Agreement has yet to be reached regarding the sanctions and/or remedies for non-compliance with the disclosure requirements. A wide range of remedies and sanctions for non-compliance is provided in the national laws of jurisdictions across the globe. These

range from administrative sanctions to the denial, revocation or finding of unenforceability of a patent.

Depending on the final form of this provision in the instrument which may result from the diplomatic conference, and its potential implementation in various countries, the sanctions could include rendering a patent unenforceable for non-compliance with the disclosure requirement. This could be analogous to the operation of the USPTO Rule 56 (37 CFR 1.56) relating to inequitable conduct.

### **Request for Comments**

The USPTO welcomes any relevant comments on the topics described in this Request for Comments. However, the USPTO is particularly interested in comments responsive to the questions below. When responding to the questions, please identify yourself.

Commenters need not respond to every question and may provide relevant information even if it is not responsive to a particular question.

### **Questions for Comment**

#### *Section I - Observations and experiences*

1. Have you or any of your members, partners, co-workers, legal representatives or clients filed for patent protection in a jurisdiction that requires disclosure of the source of genetic resources and associated traditional knowledge in a patent application seeking protection for inventions based on genetic resources (hereafter “patent disclosure requirement”)? If yes, to the extent possible, please identify the jurisdiction(s) that required disclosure and describe the circumstances and your experiences associated with satisfying the patent disclosure requirement in that jurisdiction.
2. How would you characterize the level of difficulty in complying with the aforementioned patent disclosure requirement? Please describe any anticipated or

unanticipated problems that resulted or may result from the disclosure itself or the associated requirement for the disclosure.

3. Please describe how your experiences with the patent disclosure requirement in the aforementioned jurisdiction or other jurisdictions across the globe affect your business. Where possible, please identify the jurisdiction as well as any relevant details of the patent disclosure requirement.
4. Please identify any type of patent disclosure requirement, in the context of Genetic Resources and Traditional Knowledge, you believe is necessary and any benefits or detriments stemming from a patent disclosure requirement.
5. Please identify any instances where you are aware of patent rights— yours, someone you represent or another party's— being impacted by the existence of a patent disclosure requirement, including but not limited to, any loss of rights, additional costs or other negative impacts.
6. Please share whether or not the existence of a patent disclosure requirement was (or is) a consideration in pursuing patent protection on an invention in a given jurisdiction. Please provide details in relation to relevant technologies where this may be a consideration as well as alternative actions you took or would take in lieu of pursuing patent protection in the jurisdiction.

*Section II - Need and effectiveness of a patent disclosure requirement for Genetic Resources and Traditional Knowledge*

7. Do you believe the patent system— through the use of a patent disclosure requirement in jurisdictions where such requirement exists— has been an effective regulator of access and benefit sharing for genetic resources? Please explain.

8. Do you believe that a patent disclosure requirement would enable interested groups to locate information on the use of a country's genetic resources? Please explain.
9. Where a claimed invention is based on genetic resources, please identify the appropriate range of subject matter of genetic resources that should be within the scope of a disclosure requirement.
10. Please comment on the effectiveness of the following options relating to disclosure of genetic resources and / or traditional knowledge associated with genetic resources in a patent application:
  - a) Disclosure when genetic resource information is material to patentability.
  - b) Voluntary disclosure of genetic resource information.
  - c) Disclosure requirement if the genetic resource information is known.
  - d) Mandatory disclosure requirement in all instances when an invention is based on genetic resources.
  - e) Disclosure of access and benefit sharing compliance.
  - f) Compliance/non-compliance with a disclosure requirement.
11. Please describe your views on what trigger mechanism should be used, if any, for a patent disclosure requirement pursuant to the Chair's text or the consolidated text.
12. Please describe your views on what a patent applicant should be compelled to disclose in a patent application, in the context of a patent disclosure requirement.
13. Please describe your views on whether a patent disclosure requirement should include provisions that impact the grant or the validity and enforceability of a patent in cases of non-compliance with a disclosure requirement.
14. Please describe your views on the current working text for an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional

Knowledge Associated with Genetic Resources, which has been approved for consideration by the Diplomatic Conference. Please describe recommendations, if any, for additions, deletions or changes that you would recommend to Articles 1 through 9 (“substantive articles”) from the Chair’s text and Articles 10 through 23 (“administrative provisions and final clauses”) drafted by the WIPO Secretariat, including whether any language from the “consolidated text,” a previous working text in these discussions, should be incorporated into or replace the current working text. These texts can be found at the links below:

- a) Current working text “substantive articles” (Articles 1 through 9 from the WIPO IGC “Chair’s text”), as revised in the Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in Geneva on September 4-8, 2023, is included as the Annex to document WIPO/GRTKF/IC/SS/GE/23/4 on the Decisions adopted by the committee on genetic resources and associated traditional knowledge, which can be found on the WIPO website, [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=620066](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=620066).
- b) Current working text “administrative provisions and final clauses” are contained in GRATK/PM/2, which can be found on the WIPO website, [https://www.wipo.int/edocs/mdocs/diplconf/en/gratk\\_pm/gratk\\_pm\\_2.pdf](https://www.wipo.int/edocs/mdocs/diplconf/en/gratk_pm/gratk_pm_2.pdf), with a minor revision to delete “to advise it on the matters referred to in Articles [7] and [9], and on any other matter” in Article 11.2(e), as reflected in Summary Report of the Preparatory Committee, which can be found on the WIPO website, [https://www.wipo.int/edocs/mdocs/diplconf/en/gratk\\_pm/gratk\\_pm\\_5.pdf](https://www.wipo.int/edocs/mdocs/diplconf/en/gratk_pm/gratk_pm_5.pdf).
- c) The latest consolidated text, contained in the Annex to document WO/GRTKF/IC/43/4, which can be found on the WIPO website,

[https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_43/wipo\\_grtkf\\_ic\\_43\\_4.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_43/wipo_grtkf_ic_43_4.pdf).

15. Please describe whether you believe any additional requirements, in particular a mandatory disclosure requirement relating to genetic resources and associated traditional knowledge, would negatively impact your patent filing strategy in overseas markets, your ability to protect innovation, or your business and investment strategy.

*Section III - Need and effectiveness of sui generis exclusive rights, intellectual property rights, or other methods for protecting Traditional Knowledge and Traditional Cultural Expressions*

16. Please describe your views and experiences regarding the use of *sui generis* exclusive rights to protect traditional knowledge and traditional cultural expressions.
17. Please describe your views and experiences regarding the use of intellectual property rights to protect traditional knowledge and traditional cultural expressions.
18. Please describe your views and experiences regarding the use of means or methods other than *sui generis* exclusive rights or intellectual property rights to protect traditional knowledge and traditional cultural expressions. Among other means and methods, this could include soft law, such as declarations, recommendations, best practices, toolkits, and voluntary codes of conduct.
19. Please provide your recommendations regarding how best to address unauthorized uses of traditional knowledge or traditional cultural expressions.

**Katherine K. Vidal,**

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

