March 18, 2025

Coke M. Stewart
Acting Undersecretary of Commerce for Intellectual Property
Acting Director, U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Submitted via: https://www.regulations.gov

Re: Request for Comments and Testimony on the World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (Fed. Reg. Notice 2025-01090; Docket No. PTO-C-2024-0048)

Dear Acting Director Stewart:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the Request for Comments and Testimony on the World Intellectual Property Organization (WIPO) Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (hereinafter, "the Treaty") adopted by the WIPO Member States in Geneva, Switzerland on May 24, 2024, published on January 17, 2025, in the *Federal Register*.[1]

IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers, and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for an IP system that enables innovation and creativity; and disseminating information to the public on the importance of IP rights. IPO's vision is the global acceleration of innovation, creativity, and investment necessary to improve lives.

IPO opposes adoption of the Treaty by the United States. Part of IPO's mission is to promote predictable legal systems for all industries and technologies. The predictability of the current IP legal framework encourages innovators to make significant investments of resources needed to solve some of society's greatest challenges. IPO supports the ultimate goal of fair and equitable benefit sharing contemplated by other treaties, but believes that goal is unrelated to the patent system. IPO is concerned that this Treaty risks undermining the innovation ecosystem, while doing nothing to advance the protection and equitable benefit sharing of genetic resources.

[1] Request for Comments and Testimony on the World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, 90 Fed. Reg. 5,828 (Jan. 17, 2025).

The Treaty requires disclosure of the country of origin of genetic resources and/or traditional knowledge associated with genetic resources in patent filings when such information is known. The terms of the Treaty are important to any innovative industry that uses genetic material in its research and development, including many IPO member companies. A new requirement for disclosure could impact innovators across a broad set of sectors including, but not limited to, basic research, biopharmaceutical, bioindustrial, agricultural, cosmetic, and food industries.

IPO believes that the Treaty will undermine the international innovation ecosystem and does not support the U.S. signing onto and becoming a party to the Treaty. In particular, IPO believes that becoming a party to the Treaty could have a harmful impact on innovation in the U.S. and U.S. leadership in science. IPO further believes that becoming a party to the Treaty would have no beneficial impact on U.S. businesses, consumers, or the economy.

Triggers to Disclose the Origin of Genetic Resources

IPO opposes U.S. adoption of the Treaty because it would create unpredictability and because IPO believes that burdensome disclosure requirements can discourage an applicant from filing for patent protection in jurisdictions that impose them. In lieu of pursuing patent protections, innovators could choose to protect their inventions as trade secrets, denying the public the benefit of knowledge of the invention. Alternatively, burdensome disclosure requirements may discourage innovators from pursuing research that may require the use of genetic resources.

One of the greatest uncertainties introduced by the Treaty concerns the "trigger" for when the country of origin of genetic resources and/or associated traditional knowledge needs to be disclosed. Article 3.1 of the Treaty provides that disclosure is required when the claimed invention "is based on" genetic resources.[2] The term "based on" is defined to require that the "genetic resources [1] must have been necessary for the claimed invention, and [2] that the claimed invention must depend on the specific properties of the genetic resources . . . ."[3]

IPO is concerned that the "based on" standard is subject to varying interpretations and therefore promulgates uncertainty. IPO believes that this trigger would not require the identification of genetic resources that are used as a research tool (for example, as a screening material during research) or in other ways that are ancillary to the ultimate claimed subject matter, however such exemptions are not articulated in the Treaty. Article 3 further indicates that where the country of origin is not known, the source of such genetic resources must be disclosed and, if neither is known, the applicant may file a declaration stating as much.[4] A known source may be, for example, an *ex situ* collection or other depository for genetic resources, such as the International Treaty on Plant

[2] World Intellectual Property Organization [WIPO] Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, art. 3.1, *adopted* May 24, 2024, WIPO Doc. TRT/GRATK/001.
[3] *Id.* at 3 (emphasis added).
[4] *Id.* at 4.

Genetic Resources for Food and Agriculture. Article 3.2 makes similar disclosure requirements for traditional knowledge associated with genetic resources.[5]

Scope of Genetic Resources

Another important issue to innovative companies is the lack of clarity regarding the scope of genetic resources implicated by the Treaty.

IPO appreciates the agreed footnote number 1 in the Treaty that appears to exclude human genetic resources and IPO urges the U.S. to maintain this interpretation.[6] Thus, further references to "genetic resources" in this comment refer to "non-human" genetic resources unless otherwise indicated.

Nonetheless, to the extent that the Treaty includes both (non-human) genetic resources and traditional knowledge associated therewith, it would ambiguously expand the scope of the disclosure requirement and lead to uncertainty. Traditional knowledge issues are currently being debated in different Intergovernmental Committee (IGC) meetings and should not have been included within the genetic resources subject matter for this Treaty.

Given that other United Nations forums are also still in the process of collecting views on Digital Sequence Information (DSI), attempts to include DSI as part of a disclosure requirement are also without proper resolution in the IGC and are therefore premature. This is particularly so because, as noted in other forums, identifying the source or origin of DSI could prove even more difficult because public databases from which DSI is obtained have not historically required or included such information. IPO is especially concerned that this issue could be prematurely included in the Treaty given the troubling direction of DSI discussions in the Conference of Parties to the Convention of Biological Diversity (CBD), which aims to impose what amounts to a global tax on DSI use without defining DSI or what it means to use it.

The Treaty does not expressly state that DSI can constitute genetic resources. While the definition of "source of genetic resources" expressly includes a "gene bank," genetic resources under the Treaty should be limited to physical specimens containing units of heredity, which are not encompassed by DSI within the GenBank® database.[7] This is an important issue to industry because, often, DSI information stored in online directories does not reference the genetic origin of the sequence. Additionally, DSI may represent information that is obtained or discovered much later in time from the genetic resources from which it is derived. In the separate context of access and benefits sharing, the inclusion of DSI in a definition of "genetic resource" is an issue recently debated in the

[5] *Id.*
[6] *Id.* at 3 n.1 (stating "[t]he definition of 'genetic resources' is, in line with the manner in which the term is understood in the context of the Convention on Biological Diversity, not intended to include 'human genetic resources.'").
[7] *Id.* at 3.

negotiations on a Pandemic Preparedness Treaty in the World Health Organization, as well as in ongoing negotiations in the CBD, as noted above.[8]

Another potential issue for U.S. innovators is the Article 8 review clause which commits the contracting parties to a review of the Treaty at four years after the entry into force and suggests "the possible extension of the disclosure requirement . . . to other areas of intellectual property and to derivatives and . . . other issues arising from new and emerging technologies that are relevant for the application of this Treaty."[9] It is in such review of the Treaty that the language could be revised to extend the disclosure requirement to DSI.

IPO is also concerned that the Treaty could be interpreted to countermand the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which mandates signatory countries grant patent rights for inventions that are novel, have an inventive step, and have industrial applicability.[10] IPO is concerned that the Treaty would impose a further requirement for patentability beyond the scope of the TRIPS Agreement, namely the requirement for the disclosure of the origin of genetic resources and/or associated traditional knowledge. Indeed, IPO understands that some countries have already called for amendments to the Patent Cooperation Treaty, with an aim of moving in that direction.[11] IPO believes the duty of disclosure under 37 C.F.R. 1.56 already provides robust obligations for the identification of prior art that is material to patentability.[12]

International Experiences

Finally, the USPTO requests comments on experiences with genetic resource disclosure requirements in other countries. IPO members have dealt with required disclosure of genetic resources and associated traditional knowledge in various countries, including China, India, South Korea, Brazil, and the Andean Region. Many of these national laws predate the signing of the Treaty, but are likely to serve as models for signatory states who do not currently have a comparable national law.

IPO members have found that complying with genetic resource disclosure requirements in some countries can be burdensome, expensive, and introduce uncertainty into patent law. As a result, these disclosure requirements can impede research and development or encourage the use of trade secrets, contrary to the purposes of the TRIPS Agreement.

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[8] World Health Organization [WHO] Director-General, *Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response*, art. 1(c), WHO Doc. A77/10 (May 27, 2024); Convention on Biological Diversity Dec. 16/2, U.N. Doc. CBD/COP/DEC/16/2 (Nov. 1, 2024).

[9] World Intellectual Property Organization [WIPO] Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, *supra* note 2, at 6.

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

[11] World Intellectual Property Organization [WIPO] Patent Cooperation Treaty (PCT) Working Group Eighteenth Session, *WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge*, WIPO Doc. PCT/WG/18/16 (Jan. 20, 2025).

[12] Duty to Disclose Information Material to Patentability, 37 C.F.R. § 1.56 (2023).

In China, current law requires a patent applicant disclose the direct and original source of genetic resources for any invention "accomplished by relying on genetic resources."[13] The term "genetic resources" is particularly broad and includes any material taken from human, animal, plant or microorganism which contains functional units of heredity and is of actual or potential value, and genetic information generated from the use of such material.[14] Thus, as an initial matter, China's law goes beyond the scope permitted by the Treaty through its inclusion of human genetic resources and may therefore have implications for conducting human clinical trials intended to demonstrate the safety and efficacy of new medicines. China's law also allows for the rejection of any patent right where the required information for the genetic resources, including human genetic resources, is not disclosed.[15] The Chinese law introduces uncertainty into patent prosecution.

India has enacted a disclosure requirement law that creates a significant burden on patent applicants. In India, failure to disclose or wrongly describe the source and geographical origin of biological material that is not publicly available is a ground for opposition, and ultimately revocation, of the patent.[16] In practice, the Indian Patent Office frequently raises objections under the disclosure law, regardless of whether the referenced biological material is publicly available or not. India has created a National Biodiversity Authority (NBA) to regulate use of the genetic resources of India, whereby a non-Indian person or company requires the approval of the NBA to access the genetic resources, or to include the genetic resources in a patent application in India.[17] The NBA also has the right to require benefits sharing or royalties to the Indian government, based on the use of the Indian origin genetic resources employed in the patent application.[18] The Indian law has discouraged U.S. applicants from filing patent applications in India on inventions that might require disclosure.

Conclusion

In summary, IPO opposes adoption of the Treaty by the U.S. because its ambiguous terms create uncertainty and less propensity to foster innovation, it adds onerous disclosure requirements to the patent system, and it is unnecessary in view of existing international and U.S. patentability requirements.

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[13] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020, effective June 1, 2021), art. 26 (China).

[14] Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (2023 Nian Xiuding) (中华人民共和国专利法实施细则 (2023 年修订)) [Implementing Rules of the Patent Law of the People's Republic of China] (promulgated by the State Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023), art. 29 (China).

[15] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China], art. 5 (China).

[16] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADEMARKS, GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL 2 (2017) (India).

[17] The Biological Diversity Act, 2002, §§ 3, 6 (India).

[18] The Biological Diversity Act, 2002, § 6(2) (India).

IPO thanks the USPTO for its attention to IPO's comments submitted herein and welcomes further dialogue and opportunity to provide additional comments.

Sincerely,

Krish Gupta

Krish Gupta
President