March 18, 2025

Via Electronic Submission
Coke Morgan Stewart
Acting Under Secretary of Commerce for Intellectual Property and Acting Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

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

Dear Acting Director Stewart,

The Council for Innovation Promotion (C4IP) submits this comment in response to the USPTO's Request for Comments on whether the United States should sign and implement the World Intellectual Property Organization (WIPO) Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge. After careful analysis, we must express our profound concerns regarding the United States becoming a signatory to this treaty.

By way of background, C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

We are chaired by two former directors of the USPTO, Andrei Iancu and David Kappos, who served under Presidents Trump and Obama, respectively. Our board also includes two retired judges from the Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. As a group of experts, we write to outline how joining the WIPO treaty would significantly undermine innovation, intellectual property (IP) rights, and U.S. global competitiveness.

We previously submitted a comment to the USPTO in advance of the diplomatic conference to negotiate this treaty (Docket No. PTO-C-2023-0019-0001), in which we detailed our

concerns about the detrimental effects of imposing new patent disclosure requirements on innovators.[1]

In that comment, we urged the USPTO to "lead the way in defending strong and reliable IP protections at home and abroad," noting that "WIPO's proposed [genetic resource] and [traditional knowledge] disclosure requirements would directly undermine this goal." Despite our warning — and equally strong concerns from many other groups — the previous administration failed to stop this proposal from advancing in Geneva.

We strongly recommend that you urge the Administration to correct course by rejecting this treaty, thereby defending the IP rights of American innovators and, more generally, the established merit-based system for rewarding innovation with patent protection.

Undermining U.S. Patent Law

The WIPO treaty's new disclosure requirements are fundamentally at odds with established U.S. patent law principles. For centuries, American patent law has been carefully calibrated to protect inventors from infringement while serving the public interest through requiring the disclosure of how to make and use new inventions. The cornerstones of patentability — disclosure, novelty, utility, and non-obviousness — are a key component of this delicate balance.

The treaty's new mandatory patent disclosure requirements (PDRs) for genetic resources and traditional knowledge would introduce a disruptive and unnecessary element into a system that has successfully incentivized innovation and promoted access to new inventions for over two centuries. Unlike traditional patentability requirements that focus on the merits of the invention itself, these disclosure obligations relate to matters irrelevant to an invention's technical contribution or inventive step.

This strikes at the very heart of what our patent system aims to accomplish. By conditioning patent protection on compliance with requirements unrelated to innovation, the treaty would subordinate the promotion of technological progress — a constitutional mandate — to other policy objectives.

[1] USPTO, *World Intellectual Property Organization Intergovernmental Committee Negotiations on Genetic Resources and Associated Traditional Knowledge*, 88 FR 73003 (Oct. 24, 2023), https://www.regulations.gov/document/PTO-C-2023-0019-0001.

Compromising America's Global Leadership in Innovation

America leads the world in biomedical breakthroughs for a simple reason: our strong and predictable patent system encourages investments in high-risk, transformative research. The treaty threatens this competitive edge.

First, it introduces harmful legal ambiguities. The requirement to disclose when an invention is "based on" genetic resources creates a minefield of uncertainties, notwithstanding the two-part test the treaty includes in its definition for this term.[2] While this definition purports to limit the scope of "based on" to what is material or necessary for the invention, these limitations are imprecise and will undoubtedly be subject to second-guessing, particularly for patents that are litigated. This vagueness will force companies to either over-disclose (creating significant administrative burdens) or risk their patents being invalidated later. Either way, the patent owner will face greater uncertainty and higher costs, as this issue will be contested in court even if the patent owner ultimately wins.

Second, it demands the scientifically impossible. Modern biotechnology routinely involves thousands of genetic materials that have crossed international borders multiple times.[3] Determining a definitive "country of origin" for many resources is like trying to trace a drop of water back to its original cloud. The demand simply cannot be delivered.

The treaty attempts to lessen this conundrum by allowing the patent applicant to provide disclosure of the immediate source from which the genetic resources or traditional knowledge were obtained if the original origin is not known.[4] But whether this alternative will prove sufficient will then become a fight over whether the applicant knew — or should have known — about the ultimate origin but improperly withheld it. The treaty's potential remedies make clear, for example, that fraudulent deception can be a basis for a patent to be invalidated.[5] Experience with the current U.S. doctrine that allows for invalidation based on fraudulent deception (inequitable conduct) is that it is frequently alleged and litigated in patent infringement cases, even if the factual basis for the argument is thin and unlikely

[2] "Based on" is defined to mean "that the genetic resources and/or traditional knowledge associated with genetic resources 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 genetic resources and/or traditional knowledge associated with genetic resources." World Intellectual Property Org., WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, art 2, May 24, 2024 [hereinafter "WIPO Treaty"], https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_3.pdf.

[3] Steward Redqueen, *Economic Impact of Disclosure Requirements in Patent Applications for 'Genetic Resources'-Based Innovation* 2 (Jun. 2018), https://www.ifpma.org/wp-content/uploads/2023/01/i2023_Economic-impact-DRs-for-GRs-final-report_June2018.pdf.

[4] WIPO Treaty, *supra* note 2, art. 3, 3.1(b), 3.2(b).

[5] *Id.*, art. 5, 5.4.

to prevail.[6] With this backdrop, a patent applicant can take no comfort in this supposed alternative disclosure option when it will have to prove a negative in court — that it did not know the true origin — should it ever want to enforce its patent.

Finally, new genetic resources and traditional knowledge disclosure requirements could significantly slow the patent approval process. This is not hypothetical: In Brazil and India, disclosure mandates have slowed the patent process by 2 to 4 years.[7] For startups with limited funds, such delays are not mere inconveniences — they are existential threats that can kill promising therapies before they reach patients.

Undermining International Scientific Collaboration

Many of today's most significant scientific breakthroughs emerge through international collaborative research networks.[8] Studies have demonstrated that cross-border scientific partnerships produce particularly impactful innovations, especially in fields like biotechnology and pharmaceuticals. The treaty threatens this vital collaboration model.

By imposing onerous documentation and disclosure requirements, the treaty would erect new barriers between researchers working across national boundaries. Scientists could face complex questions about ownership, attribution, and disclosure requirements for genetic resources utilized in joint research. This administrative complexity would inevitably chill collaboration, particularly for smaller research institutions and companies that lack substantial legal resources.

Other countries' adoption of the treaty's disclosure requirements could also create asymmetric burdens for researchers from different countries, with potentially greater obstacles for U.S.-based innovators seeking to collaborate with partners in biodiversity-rich regions. The resulting disincentives to collaboration could ultimately slow the pace of innovation in critical areas like drug discovery, agricultural improvement, and environmental technology.

[6] Eric E. Johnson, *The Case for Eliminating Patent Law's Inequitable Conduct Defense*, 117 Columbia L.Rev. Online 1, 2 (2017) ("[I]n the real world, the inequitable conduct defense can make a mess of things, driving up litigation costs, changing settlement dynamics, perverting patent economics, elevating strategic behavior, and creating a sideshow of mudslinging for the jury."), https://columbialawreview.org/wp-content/uploads/2017/01/Johnson-final1.pdf.

[7] Redqueen, *supra* note 3.

[8] R. Jay Widmer et al., *International Collaboration: Promises and Challenges*, 6 Rambam Maimonides Med J. (Apr. 29, 2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4422451/.

International Legal Conflicts

In addition to introducing vague new requirements for patentability that diverge from longstanding legal principles, the treaty raises serious compatibility concerns with existing international agreements. In several respects, it may conflict with well-established global intellectual property frameworks, effectively attempting to amend them sub silentio.

- **The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)** was established to provide a stable and predictable foundation for global innovation, ensuring that intellectual property protections incentivize investment in scientific progress while facilitating international collaboration.

  Under Articles 27.1 and 29, WTO members must make patents available for "any inventions . . . provided that they are new, involve an inventive step, and are capable of industrial application" provided that "an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[9] The treaty under consideration effectively alters the disclosure requirement — inserting a new mandatory disclosure of the origin of genetic resources or traditional knowledge — that arguably conflicts with these core TRIPS principles that are focused on scientific merit.

  Furthermore, Article 27.1 of TRIPS prohibits discrimination in patent availability based on "field of technology." By imposing burdensome new obligations primarily on biopharmaceuticals and other industries that rely on genetic resources, the treaty may be inconsistent with this non-discrimination principle. Beyond its immediate impact, such a departure from TRIPS could set a concerning precedent, opening the door for future carve-outs that weaken the global patent system's uniformity and reliability.

  While the treaty includes a provision in Article 5.3 stating that patents shall not be revoked "solely" for failure to comply with disclosure requirements, this safeguard is ambiguous at best. It leaves room for national courts and patent offices to impose indirect penalties, such as denying injunctions or awarding only nominal damages, effectively stripping patents of their enforceability while maintaining their formal validity.[10] The following provision, moreover, makes clear that fraudulent withholding

[9] Uruguay Round Agreement: TRIPS, World Trade Organization, arts. 27.1, 29, Apr. 15, 1994, https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

[10] WIPO Treaty, *supra* note 2, art. 5, 5.3.

or misrepresentation of this information can be the basis for invalidation.[11] As discussed above, this alone will provide the basis for substantial litigation over whether fraud has occurred, even if actual instances of fraud are rare.

- The **Patent Cooperation Treaty (PCT)**, ratified by 158 countries, including the United States, was designed to create a streamlined and harmonized international patent filing system, reducing barriers to global patent protection and ensuring consistency across jurisdictions.[12] The PCT does not mandate genetic resource disclosure as a condition for filing a patent application. The treaty under consideration may disrupt this established framework by introducing such a requirement should an applicant wish to proceed with patent prosecution in member states that have ratified this WIPO treaty, creating uncertainty for applicants navigating the international patent process.

  Notably, the WIPO treaty appears to acknowledge this likely incompatibility by including a request for the relevant international body to consider whether amendments to the PCT are necessary. This acknowledgment underscores the tension between the two frameworks, raising concerns about whether the treaty could create conflicting obligations for PCT member states and disrupt the international patent filing system that has functioned effectively for decades.[13]

A Divergent Vision

The TRIPS and PCT frameworks were established to foster a balanced global patent system — one that rewards innovation, facilitates knowledge sharing, and provides a stable foundation for cross-border scientific collaboration. These agreements reflect a broad international consensus that strong, predictable intellectual property protections are essential for advancing science and technology.

By contrast, the treaty under consideration risks undermining this vision by introducing new legal uncertainties, imposing disproportionate burdens on certain industries, and creating potential conflicts with existing international obligations. Rather than strengthening global innovation, the treaty could discourage investment, complicate international partnerships, and slow the pace of critical research in fields like biotechnology and medicine.

[11] *Id.* at 5.4.

[12] *WIPO-Administered Treaties*, World Intellectual Property Org., https://www.wipo.int/wipolex/en/treaties/ShowResults?search_what=C&treaty_id=6 (last visited Mar. 14, 2025).

[13] WIPO Treaty, *supra* note 2, art. 7.

If the goal is to ensure equitable sharing of genetic resources, the treaty's approach is not just flawed — it is counterproductive. More constructive alternatives exist, including voluntary disclosure mechanisms that support transparency without introducing excessive legal risks and bilateral agreements tailored to sector-specific needs, ensuring that resource-sharing efforts align with scientific and economic realities.

Protecting Innovation, Rejecting the Treaty

Rather than signing on to a treaty and adopting policies that jeopardize innovation, the United States should continue to champion a patent system that protects inventors, encourages investment, and drives technological progress.

Given these concerns, C4IP urges the United States to decline to sign this treaty and encourage other countries to do the same, thereby preventing the treaty from entering into force. We appreciate the opportunity to provide input and welcome further engagement on this critical issue.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)