January 22, 2024

Via Electronic Submission
The Honorable Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property and Director
of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Docket No. PTO-C-2023-0019

Dear Director Vidal,

I write today in the hopes that the USPTO will reject a dangerous proposal from the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to implement genetic resources (GR) and traditional knowledge (TK) disclosure requirements for patent applicants.

As Americans, we are deeply fortunate to live in a country that, from the very beginning, has acknowledged the importance of intellectual property (IP) rights. Our nation's founders rightly understood that these rights are a precondition for human flourishing. For this reason, they enshrined the notion of patent protections in the Constitution, paving the way for the creation of the U.S. Patent and Trademark Office (USPTO), which, over the course of nearly two centuries, has set the international gold standard for patent evaluation and enforcement.

Like you, I have the privilege of working for an organization that is committed to the preservation of strong and effective IP rights: the Council for Innovation Promotion (C4IP). As C4IP's executive director, I work every day to remind lawmakers, regulators, and the public alike that innovation is our nation's lifeblood, and what makes innovation possible are strong IP protections.

On the surface, the IGC's proposal appears to deal only with the narrow issue of how countries can better protect GR and TK. In reality, the plan would have devastating ripple effects across the global innovation ecosystem.

Devising new technologies, then testing, refining, manufacturing, marketing, and distributing them, is laborious, time-intensive, expensive, and -- more often than not -- destined to failure. Innovative work, especially in cutting-edge fields such as medicine, technology, and green energy, requires substantial R&D outlays. Without IP protections, inventors couldn't make the investments needed to develop new technologies that meet essential public needs, create new jobs, and save lives.

The IGC's mandatory GR/TK disclosure proposal risks upending this delicately balanced system, introducing additional risks and uncertainties that could dissuade researchers from trying to patent new inventions in the first place. In trying to fabricate a new role for the USPTO and its counterparts around the world, the proposal would subject inventors to cumbersome regulatory barriers, ultimately leading to fewer discoveries ever making it to market.

For IP protections to be effective, they must be predictable, stable, and strong. Inventors are most confident and willing to take risks when they have a clear understanding of what's required for a patent to win approval. Yet the IGC's draft language -- which would force patent applicants in WIPO member states to disclose the sources and origins of all GR and TK relevant to their inventions -- would inject inherently vague and arbitrary standards into the patent application process. In so doing, it would undermine the predictability of IP protections the world over.

There is no clear or universally agreed upon definition of what constitutes all GRs or TK in an invention, and trying to comprehensively identify, source, and disclose them is an arduous task which could add years to the technology development process. Where they have been tried, such as in Brazil and India, patent disclosure requirements have done little to promote equity in trade and development, while doing much to heighten the costs and risks of innovation.[1] Exporting these policies to all WIPO member states is a recipe for disaster.

Inventors will struggle to determine when GR and TK disclosure requirements have been met. And even if an inventor does disclose all relevant GR and TK sources and their patent application is approved, disclosure rules create new opportunities for post-grant challenges and litigation.

The IGC's proposal leaves a number of important questions unanswered. For instance, what happens when one country adheres to a more rigorous disclosure standard than another? Does the inventor risk sanctions for failing to comply with ambiguous and shifting requirements that will inevitably vary from market to market?

1 *Economic Impact Of Disclosure Requirements In Patent Applications For 'Genetic Resources'-Based Innovation* IFPMA (June 2018), https://www.ifpma.org/wp-content/uploads/2023/01/i2023_Economic-impact-DRs-for-GRs-final-report_June2018.pdf.

Existing international trade agreements are much better suited to the task of ensuring equitable and sustainable access to GR and TK than are patent-issuing agencies that were founded for an altogether different purpose. For example, the Convention on Biological Diversity (CBD) already provides an effective framework for sharing genetic resources and knowledge on fair and equitable terms.[2]

The USPTO must lead the way in defending strong and reliable IP protections at home and abroad. WIPO's proposed GR and TK disclosure requirements would directly undermine this goal.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

2 *The Nagoya Protocol on Access and benefit-sharing* Convention on Biological Diversity (2023), https://www.cbd.int/abs/.