

January 18, 2024

The Honorable Kathi Vidal
Director United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Vidal

Thank you for the opportunity to provide these comments in response to USPTO's request for input on the upcoming meetings at the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore.

I am a resident scholar with the Institute for Policy Innovation, a 37-year-old Texas-based nonprofit NGO promoting economic growth and innovation. I am very familiar with and appreciative of USPTO's commitment to protecting patent rights and ensuring American leadership in such areas as the life sciences and biotechnology. It is clear that a strong intellectual property framework benefits our economy in a wide range of areas. I am thankful for USPTO's efforts to promote and sustain such a framework.

That's why I'm troubled by the initiative currently under way at the World Intellectual Property Organization. The proposal would require additional information in patent applications specifying the "genetic resources" involved in an invention and their geographical origins. These proposed new Patent Disclosure Requirements (PDRs) would weaken intellectual property rights and threaten American innovation.

Proponents argue that these requirements would increase the flow of resources into countries of origin. In fact, the opposite would likely happen, as researchers seek to avoid use of genetic resources from countries with especially burdensome requirements or questionable claims of prior use.

Indeed, I recall that several years ago Hindu scholars were combing through the Vedas in an effort to find any reference to plants, animals or other substances they might use to claim that the active ingredient in some new drug was really based on Hindu traditional medicine. Behind the scheme was an effort to demand royalties from pharmaceutical companies, even if there had been no reliance on Vedic literature. If the United States were to affirm WIPO's effort to add genetic resources and other information to patent disclosures, it would break decades of precedent.

Implementing PDRs for genetic resources would increase bureaucracy and red tape in global patent and licensure processes. It would inject a high degree of legal uncertainty into an

already complex patent application system, deterring private sector investment. Additionally, enforcing compliance with the PDR would slow down the patent application process and impose heavy additional burdens of evaluation on the USPTO.

Even more troubling, the addition of PDRs may allow countries to take advantage of the scientists and companies conducting research and development on site. The prospect of countries levying arbitrary or burdensome fees or demanding royalties could discourage investment into the very countries WIPO is interested in benefiting. American pharmaceutical and technological leadership is a result of strong partnerships both domestically and internationally. The proposed new PDRs might create perverse incentives undermining these partnerships, leading to a breakdown of international cooperation.

Unfortunately, this initiative at WIPO is only the latest in a string of international and home-grown efforts to weaken American IP protections. The World Trade Organization is currently considering a waiver of patent protection for all COVID-19 diagnostics and therapeutics. It would follow a precedent-setting decision in 2022 to void international patent rights on COVID-19 vaccines. Domestically, an administration interagency group has suggested that under existing law the government has the new-found authority to seize and relicense patents on inventions derived however slightly from government-funded research whenever bureaucrats deem the commercial product's price is too high.

All of these efforts will chill investor confidence and hamper innovation, even if some eventually prove to be illegal or unsuccessful.

Through both Republican and Democratic administrations, protecting patent rights has been a top priority of the U.S. government because IP rights are foundational to our economy. That bipartisan commitment to IP has made the United States a global leader in life sciences investment.

U.S. opposition to this WIPO proposal would help restore confidence in the commitment of the government to protect intellectual property at home and globally. I urge you to abandon any efforts that would serve to undermine the country's long and well-founded commitment to ensuring IP protections.

Sincerely,

Merrill Matthews, Ph.D.
Resident Scholar
Institute for Policy Innovation