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Request to Testify and Hearing Statement of the Intellectual Property Owners Association (IPO)

WITNESS

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Remote

HEARING STATEMENT

I am pleased to be with you today. My name is John Todaro and I am appearing as a representative of the Intellectual Property Owners Association, also known as "IPO." On behalf of IPO and its members, thank you for the opportunity to testify today and for your continued work to ensure that international agreements safeguard the intellectual property rights of inventors, in particular U.S.-based inventors and innovators.

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, IP rights. IPO membership includes over 125 companies and spans over 30 countries. IPO members make vital contributions to America's economic success by developing the advances that drive exports and create jobs. Innovators assume considerable risks and rely on IP to protect investments in new technology.

In the Federal Register Notice dated January 17, 2025, the USPTO sought public comments as to whether the U.S. should adopt the World Intellectual Property Organization (WIPO) Treaty on

Intellectual Property, Genetic Resources and Associated Traditional Knowledge ("the Treaty") adopted by the WIPO Member States in Geneva, Switzerland on May 24, 2024.

IPO opposes adoption of the Treaty by the U.S. because it imposes unclear and burdensome disclosure requirements that may discourage applicants from filing for patent protection in the U.S. and discourage U.S.-based innovators from pursuing research that requires the use of genetic resources.

The Treaty's "trigger" requirement, which sets forth the standard for when the country of origin of genetic resources and/or associated traditional knowledge needs to be disclosed, would introduce uncertainty into the U.S. patent system. Article 3.1 of the Treaty provides that disclosure is required when the claimed invention "is based on" genetic resources. 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 . . . ." IPO is concerned that the "based on" standard is subject to varying interpretations and therefore, if adopted, may lead to uncertainty.

Further, IPO believes that this trigger does not require applicants to identify genetic resources that are used as a research tool—for example, as a screening material during research. However, such exemptions are not articulated in the Treaty, leading to more potential uncertainty during patent prosecution.

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 from disclosure and IPO urges the U.S. to maintain this interpretation. Nonetheless, to the extent that the Treaty includes both (non-human) genetic resources and traditional knowledge associated therewith, the Treaty ambiguously expands the scope of the disclosure requirement, leading to uncertainty. Traditional knowledge issues are currently being debated in different Intergovernmental Committee (IGC) meetings and including them within the Treaty's subject matter only adds more uncertainty for patent filers.

IPO also opposes adoption of the Treaty on the grounds that Digital Sequence Information, or "DSI," could prematurely be included in the Treaty as part of a disclosure requirement. Identifying the source or origin of DSI could prove even more difficult than actual genetic resources because public databases from which DSI is obtained have not historically required or included such information. Additionally, DSI may represent information that is obtained or discovered much later in time than the genetic resources from which it was derived. IPO also notes that, 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 negotiations on a Pandemic Preparedness Treaty in the World Health Organization, as well as in ongoing negotiations in the Convention of Biodiversity.

IPO is also concerned that the Treaty could be interpreted to countermand provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, the TRIPS Agreement. TRIPS mandates that signatory countries grant patent rights for inventions that are novel, have an inventive step, and have industrial applicability. IPO is concerned that the Treaty imposes a requirement for patentability beyond the scope of the TRIPS Agreement, namely 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.

IPO believes that the Treaty will endanger the predictability of patent law. The predictability of the current IP legal framework enables and encourages innovators to make significant investments of resources needed to solve some of society's greatest challenges by supporting research and development in many fields. Therefore, IPO members have a strong interest in a predictable patent law system for all industries and technologies.

For these reasons, IPO believes that the U.S. 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.

Despite its opposition to adoption of the Treaty, IPO nevertheless supports the ultimate goal of fair and equitable benefit sharing. However, IPO believes that this goal is unrelated to the patent system and that this Treaty risks undermining the innovation ecosystem while doing nothing to advance the protection and equitable benefit sharing of genetic resources.

In conclusion, innovation-driven jobs depend on high quality IP systems. Effective IP protection requires predictability for American innovators. Predictability enables investments in research and development and the sharing of information among partners. The U.S. should not adopt the Treaty because it endangers this predictability and the system that relies upon it.

A predictable IP system helps sustain and grow America's economy and provide new innovations to meet global challenges. On behalf of IPO, thank you again to the USPTO for its efforts to promote an IP framework that encourages innovation and creativity.