8 September 2017

Cristiana Pașca Palmer
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques St., Suite 800
Montreal, QC, H2Y 1N9
Canada

RE: Proposed Application of Digital Genetic Sequence Information Under the Nagoya Protocol

Dear Secretary Palmer:

Intellectual Property Owners Association (IPO) writes to comment on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention, and for the objective of the Nagoya Protocol. IPO provides comments in response to your 25 April 2017 request, for the fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) and for the third meeting of the Conference of the Parties to the Nagoya Protocol.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes around 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans more than 30 countries. IPO advocates for effective and affordable IP ownership rights and provides a wide array of services to members, including supporting member interests relating to legislative and international issues; and analyzing current intellectual property issues.

CBD's three objectives are to: 1) conserve biological diversity, 2) have sustainable use of its components, and 3) provide appropriate access to genetic resources with the fair and equitable sharing of benefits arising out of their use (ABS). The Nagoya Protocol's objective is to provide a transparent legal framework for the fair and equitable sharing of benefits arising out of the use of genetic resources. IPO generally supports the principles established by the CBD and the Nagoya Protocol regarding appropriate access to genetic resources and the fair and equitable sharing of benefits arising from their use. However, implementation of programs to achieve these goals requires careful consideration of potential unintended consequences. As detailed below, IPO strongly opposes proposals to include digital genetic sequence information within the scope of genetic resources covered by the CBD or Nagoya Protocol.

The Nagoya Protocol was carefully negotiated over the course of six years, resulting from discussions on ABS that have spanned well over a decade. It was agreed and reiterated in the Nagoya Protocol that its scope is limited to those genetic resources covered by the CBD. According to Article 1 of the Nagoya Protocol, its objective is to ensure "fair and equitable

sharing of the benefits arising from the utilization of genetic resources…." As noted in Article 2 of the Nagoya Protocol, terms defined in the CBD would continue to have the same meaning in the Protocol. As such, "genetic resources," as defined in the Convention, is limited to "genetic material," which must be "material of plant, animal, microbial or other origin **containing functional units of heredity**."

During the negotiations of the Nagoya Protocol, a technical expert group convened to provide further clarity as to the potential scope of the instrument acknowledged that cells and other "parts of organisms" might contain DNA or RNA – the functional units of heredity. It was also acknowledged that the definition of terms defined in the Convention would be controlling, and any renegotiation of these terms would be impractical.[1] As a result, although there might be some question as to whether certain organisms do or do not contain functional units of heredity, it cannot be disputed that genetic sequence **information** does not and cannot contain such functional units of heredity.

Much of the genetic sequence information contained in gene banks or databases is neither eligible for patent protection or subject to other legal obligations in many countries, and is therefore public and freely available for any potential research efforts. Therefore, to put new requirements on the use of such information would be tantamount to a retroactive access and benefit sharing obligation.

In addition to the clear scope limitations existing under the CBD and the Nagoya Protocol, there are numerous practical issues that would make scope expansion to include genetic sequence information problematic. A primary issue with integrating access to digital genetic sequences under the scope of the Nagoya Protocol lies in the logistics of reliably determining the physical source of any given genetic sequence. As part of common scientific practice, when a new genetic sequence is discovered, it is published in one or several of numerous available public sequence databases, such as the GenBank, without independent verification. In many such cases, the difficult sequencing work has already been performed, and the digital sequence information has been available in these databases for years. Because the annotated information associated with a sequence has not been independently verified, it would be nearly impossible to verify the accuracy of its stated origin.

These questions are further complicated by the fact that genetic sequences are digitized, and digital information is inherently more difficult to police than physical genetic resources.

As an example of the difficulties associated with introduction of new obligations on genetic sequence information, let us imagine that a new strain of mouse is identified, which has the potential to contribute new models for human disease. There is no question that access to the mouse itself is subject to obligations of prior informed consent for access, typically arranged via mutually agreed terms. In this example, the user identifies a novel target gene that is associated with the expression of a disease, such as Parkinson's disease, a neurological disorder for which there is no cure. In many countries, the sequence of that gene would not be patentable, as it would be unaltered from its native form. The policy reasons for such patenting restrictions have been clearly articulated by courts and governments—naturally occurring discoveries are already

[1] UNEP/CBD/WG-ABS/7/2

freely available, and their availability for future research should not be preempted. If the target gene sequence is made available in a gene database, it is available for use by any scientist wishing to access it.

The access to the mouse (containing tangible genetic resources) would be subject to the ABS laws of the provider country. However, if genetic sequence information were also subject to the Nagoya Protocol, are subsequent research uses of that sequence subject to the national laws of the user country, where the genetic sequence was first isolated and identified, or to the national laws of the provider country, from which the physical genetic resources were obtained? Is this dependent on the type of agreement between the user and provider? If the agreement did not expressly require limits on genetic sequence information, does the use of that sequence information nonetheless require adherence to ABS laws? Which national laws should be applicable – the laws of the user country, the provider country, or the country in which the ultimate research was conducted? As the genetic sequence information is public and freely accessible, what if the results of that research lead to further subsequent utilization before a product is developed? As between the provider of the physical resource, the initial user and provider of the sequence information, and all subsequent users of the sequence information, which entity in the chain should be entitled to benefits? Could the use of this information come with multiple benefit sharing obligations?

The above scenarios highlight the impracticality of verifying and enforcing the proposed new scope of the regulations and the strong possibility that conditioning access to such genetic sequence data on undefined benefit-sharing obligations will lead to a reduction in sharing of information, and ultimately, the benefits received by the rest of the world. The unknown costs of benefit-sharing with the provider country would likely serve as a disincentive for collaborative research and development. This is especially troublesome in scenarios when time is of the essence, such as the need to produce vaccines or medicines in the event of a pandemic or other emergency.

IPO reiterates its strong objection to the proposal for restricted access to digital sequence information or required benefit sharing from use of publicly-available information, due to the uncertainties created by such a system and the potential negative impact on scientific research. The proposal would impede the flow of information that is, in large measure, already considered publicly available, and would frustrate the CBD objectives of promoting cooperation in scientific advances and technology transfer.

Sincerely,

Mark W. Lauroesch
Executive Director