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Dr. Cristiana Paşca Palmer, Executive Secretary
Convention on Biological Diversity
413, Saint Jacques Street, suite 800
Montreal QC H2Y 1N9
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By electronic mail (secretariat@cbd.int)

Re: Potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention, *comments submitted by Third World Network*

Dear Dr. Palmer:

In response to your invitation pursuant to decision XIII/16, paragraph 2, Third World Network offers the following comments "potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention."

Digital sequence information on genetic resources (DSI) [1] has long-term implications across the three objectives of the Convention, in the nearer term particularly for the third objective, fair and equitable sharing of benefits derived from the use of genetic resources, to which we will at present direct the majority of comments.

Sequence information and fair and equitable sharing of benefits arising from the use of genetic resources

Most urgently for the Convention at present with respect to DSI are questions of fair and equitable sharing of benefits arising from the use of genetic resources. Gene segments, genes and, indeed, entire organisms of high economic value (e.g. vaccine viruses) are now synthesized from DSI that may be exchanged electronically, meaning that organisms and genetic variants can effectively cross borders without physical biological material changing hands.

In the area of microbial genetic diversity, for example, in 2002, synthesis of poliovirus from data was considered a significant technological advance. Yet poliovirus is a mere ~7750 bases long. Fifteen years later, at the end of 2017, the Synthetic Yeast Genome Project anticipates creating an

1 We note that terminology will be reviewed and here use "DSI" in the interest of clarity.

entire 12 million base yeast strain from sequence data. The length of the largest wholly synthetic genome will have grown in 15 years from 7,750 bases to 12 million – over 1500 times as long.

Or course it is not necessary to synthesize an entire genome in order for DSI to generate benefits. Individual genes synthesized from DSI and inserted into living organisms can be of enormous value, particularly in industrial, agricultural and medical applications. For example, the gene(s) encoding a valuable industrial enzyme or therapeutic component of a medicinal plant may be synthesized from DSI and inserted into microbes for production in fermentation vats. Unlike in the past, such uses of DSI may increasingly be accomplished without accessing the microbe (or plant, animal, etc.) itself or obtaining prior informed consent (PIC) and mutually agreed terms (MAT) from the originators of the genetic resources and knowledge holders.

As many access and benefit sharing laws, policies, and agreements are predicated on physical transfers of material, these may not be applicable to DSI in their current forms. This is a large problem for ensuring fairness and equity in use of genetic resources that is poised to continue growing as the cost of sequencing diminishes and tools for storage and manipulation of DSI are further developed.

If the CBD and its Parties to do not update their approaches to ABS to account for the potential for DSI to be used without benefit sharing, the Convention's third objective will be very seriously undermined, with serious consequences for the CBD as a whole.

Without exaggeration, our view is that with the present rate of technological development, the free-for-all in utilization of DSI poses an existential threat to the Convention.

Recommendations

1. In addressing the problems that the combination of DSI and synthesis technologies pose to fair and equitable sharing of benefits, the Convention should adopt the approach that sequence data be considered the equivalent of biological material. Such a position was already put forward by many developing country Parties at COP 13. In other words, users of DSI should, in general, be subject to the same benefit sharing obligations as users of the biological materials that are the source of that DSI. In some cases, genetic resource providers may choose to make DSI available without the underlying biological material and, in such instances, these providers should be fully enabled to ensure the application of obligations that will result in fair and equitable benefit sharing.

Thus, when biodiversity is sequenced – for example, a collection of the diversity of medicinal plants or extremophiles – if and when such information is shared and/or placed in databases, due consideration must be given, and steps taken, to ensure that users of that data are obligated to share benefits, and that the rights of genetic resource providers, particularly indigenous peoples and local communities (IPLCs) are protected.

2. Importantly, providers, especially in developing countries, need to maintain awareness that transfers of non-reproductive materials – e.g. leaf matter or killed cell cultures – typically are potential transfers of DSI (if the recipient extracts and sequences nucleic acids, at the time of transfer or if the samples are preserved at a future date). Thus, even transfers of "dead" biological materials can give rise to the generation of DSI that may lead to the utilization of those genetic resources in biological systems again.

3. DSI should be understood to include sequences of DNA and RNA in all their forms, as well as the sequences of amino acids and accompanying characterization information. Like DNA and RNA sequences, sequences of the amino acids that nucleotides encode are valuable and can be used to replicate and modify natural compounds and in design of biological systems. Not covering all of these items within the CBD's treatment of ABS and DSI will result in immediate loopholes.

4. The CBD should explore how repositories of DSI, such as microbial collections, botanical gardens, academic institutions, etc., and particularly large databases such as Genbank and the European Nucleotide Archive, can require users to agree to benefit sharing as a precondition of access to DSI. The CBD may, in collaboration with other relevant intergovernmental bodies, consider the development of provisions for such user agreements (e.g. "click-wrap" terms and conditions) for databases, and develop recommendations on how databases should be required to implement them.

5. If such rules are developed and implemented, it may be these case that not every use of DSI in a database will incur a specific benefit sharing obligation, and importance should be attached to identifying triggers. It is important, however, that general ABS obligations be imposed prior to any access, as retroactive ("downstream") tracing of utilization of sequences is less practical and loaded with difficulties and potential pitfalls.

6. The CBD should study and consider developments in the gene foundry and synthesis equipment industries and their implications for DSI and ABS. The gene foundry and synthesis equipment industries are largely unregulated, even to the extent of copies of some of the world's most dangerous pathogens being reproduced from DSI, causing alarm in security circles. Put simply, synthesis equipment does not care what it is synthesizing, from neither safety nor fairness and equity perspectives, and companies that commercially synthesize DSI generally do not consider CBD-relevant obligations associated with the nucleotide sequences they are producing.

Further, efforts are underway to create smaller, faster, cheaper, and more portable machines to synthesize ever-larger molecules from DSI, including machines that synthesize double stranded DNA and that can be directed by e-mail. These so-called "digital-to-biological converters" aim to expeditiously and easily complete the loop from biological to DSI and back to biological. These aim to be portable and easy to operate, broadening the possibilities to use DSI to modify and recreate organisms – particularly microorganisms – anywhere.

7. Socio-economic and sustainable use impacts of the use of DSI – e.g. on vanilla and vetiver farmers – have been described. The CBD will continually need to bear in mind that the recording of DSI is not sustainable use *per se*, and that the potential disruption or collapse of IPLC systems engendered by unrestrained use of DSI could more broadly impact conservation and sustainable use of genetic resources by economically undermining communities that conserve and sustainably utilize a wide variety of biodiversity.

8. Likewise on conservation, it might for example be argued that placement of DSI in databases "in silico" constitutes a form of protection against loss of genetic diversity. Yet, at the same time, undue reliance on DSI as a conservation (or even use) mechanism may sap government resolve and even drain away resources and effort toward *in situ* conservation, interrupting and devaluing the work of indigenous peoples and local communities that develop, conserve, and use biodiversity.

9. Use of DSI also poses novel challenges to the control of invasive alien species (IAS). Whereas measures to prevent the introduction of IAS traditionally rely on physical inspections and barriers at

borders, synthesis of DSI offers the possibility to leapfrog borders and – deliberately or accidentally introduce novel species and populations.

Thank you for the opportunity to make these comments. Third World Network looks forward to the result of this information gathering exercise and will continue to monitor and participate in the CBD's work on DSI.

Sincerely,

Chee Yoke Ling
Director of Programmes